Actavis

Mary-Lou Schoonover
DEA Compliance Analyst

T 862 261 7486
F 862 261 7927
Mary-Lou.Schoonover@actavis.com

Actavis, Inc.
400 Interpace Parkway, Building A
Parsippany, NJ 07054
www.actavis.com

April 14, 2014

Florida Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics Program
Attn: Rebecca Burnett
1940 North Monroe Street
Tallahassee, FL 32399-0783

Re: Actavis Inc. (#261154) and Actavis Kadian LLC (#261153)

Dear Ms. Burnett:

The purpose of this letter is to inform you that our facility located at 60 Columbia Road in Morristown, NJ was closed on February 14, 20014. This facility was the corporate headquarters for Actavis prior to the corporation being purchased by Watson Pharmaceuticals, Inc.

All closeout activities have been completed at the site and all business has been relocated to the corporate headquarters of Actavis, Inc. at 400 Interpace Parkway, Parsippany NJ 07054.

No products were physically stored at the Morristown location. All products are stored and shipped through our distribution center, Actavis Pharma, Inc. located at 605 Tri-State Parkway, Gurnee, IL 60031. A current copy of the DEA distributor registration is attached.

As part of this process, we would like to relinquish the following licenses: #261154 registered to Actavis Inc. and #261153 registered to Actavis Kadian LLC. We are returning the original license permits issued by the Department for this facility.

Should you have any questions or concerns, please feel free to contact me directly at 862-261-7486 or by email to mary-lou.schoonover@actavis.com

Sincerely,

Mary-Lou Schoonover,
DEA Compliance Analyst

Enclosures

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RW0237900	06-30-2014	$1523

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	DISTRIBUTOR	04-16-2013

ACTAVIS PHARMA, INC.
605 TRI-STATE PARKWAY
GURNEE, IL 60031

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

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Form DEA-223 (05/04)

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C# 6344069

STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

SEQ# L12090700667

DATE	BATCH NUMBER	LICENSE NBR
09/07/2012	120103601	261154

The NON-RESIDENT RX DRUG MANUFACTURER
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: SEP 30, 2014

ACTAVIS INC.
60 COLUMBIA RD
BLDG- B
MORRISTOWN NJ 07960

RICK SCOTT
GOVERNOR

KEN LAWSON
SECRETARY

DISPLAY AS REQUIRED BY LAW

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C# 6344070

STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

SEQ# L12090700668

DATE	BATCH NUMBER	LICENSE NBR
09/07/2012	120103600	261153

The NON-RESIDENT RX DRUG MANUFACTURER
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: SEP 30, 2014

ACTAVIS KADIAN LLC
60 COLUMBIA RD
BLDG-B
MORRISTOWN NJ 07960

RICK SCOTT
GOVERNOR

KEN LAWSON
SECRETARY

DISPLAY AS REQUIRED BY LAW

Shipment Receipt

Address Information

Ship to:	**Ship from:**
Rebecca Burnett	Mary-Lou Schoonover, DEA Compliance
Florida Dept of Business/Prof Reg	Actavis Pharmaceuticals
Drugs/Devices/Cosmetics Division	Morris Corporate Center III
1940 North Monroe Street	400 Interpace Parkway, Bldg DFlr 2
TALLAHASSEE, FL 32399	Parsippany, NJ 07054
US	US
850-717-1800	8622617486

Shipment Information:
Tracking no.: 798588015356
Ship date: 04/18/2014
Estimated shipping charges: 8.02

Package Information
Pricing option: FedEx Standard Rate
Service type: Standard Overnight
Package type: FedEx Envelope
Number of packages: 1
Total weight: 1 LBS
Declared Value: 5.00 USD
Special Services:
Pickup/Drop-off: Use an already scheduled pickup at my location

Billing Information:
Bill transportation to: Watson Pharmaceuticals Inc-818
Your reference: 500300
P.O. no.:
Invoice no.:
Department no.:

Thank you for shipping online with FedEx ShipManager at fedex.com.

Please Note

AC# 6344070

STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

SEQ# L12090700668

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Expiration date: SEP 30, 2014

ACTAVIS KADIAN LLC
60 COLUMBIA RD
BLDG-B
MORRISTOWN NJ 07960

RICK SCOTT
GOVERNOR

KEN LAWSON
SECRETARY

DISPLAY AS REQUIRED BY LAW

AC# 6344070

STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

SEQ# L12090700668

DATE	BATCH NUMBER	LICENSE NBR
09/07/2012	120103600	261153

The NON-RESIDENT RX DRUG MANUFACTURER
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: SEP 30, 2014

ACTAVIS KADIAN LLC
60 COLUMBIA RD
BLDG-B
MORRISTOWN NJ 07960

RICK SCOTT
GOVERNOR

KEN LAWSON
SECRETARY

DISPLAY AS REQUIRED BY LAW

STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS (850) 487-1395
1940 NORTH MONROE STREET
TALLAHASSEE FL 32399-0783

ACTAVIS KADIAN LLC
60 COLUMBIA RD
BLDG-B
MORRISTOWN NJ 07960

Congratulations! With this license you become one of the nearly one million Floridians licensed by the Department of Business and Professional Regulation. Our professionals and businesses range from architects to yacht brokers, from boxers to barbeque restaurants, and they keep Florida's economy strong.

Every day we work to improve the way we do business in order to serve you better. For information about our services, please log onto **www.myfloridalicense.com**. There you can find more information about our divisions and the regulations that impact you, subscribe to department newsletters and learn more about the Department's initiatives.

Our mission at the Department is: License Efficiently, Regulate Fairly. We constantly strive to serve you better so that you can serve your customers. Thank you for doing business in Florida, and congratulations on your new license!

STATE OF FLORIDA AC# 6344070
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

261153 09/07/12 120103600

NON-RESIDENT RX DRUG MANF
ACTAVIS KADIAN LLC

HAS REGISTERED under the provisions of Ch.499
Expiration date: SEP 30, 2014 L12090700668

DETACH HERE

SIGNATURE

Florida Department of
Business & Professional Regulation

Drugs, Devices and Cosmetics
Reginald D. Dixon, Executive Director
1940 North Monroe Street
Tallahassee, Florida 32399-1047
Phone: 850. 717.1800

Ken Lawson, Secretary

Rick Scott, Governor

March 7, 2012

Attention: Compliance Department

RE: Florida Controlled Substance Distribution Reporting
Industry Compliance Reminder

To Whom It May Concern:

Effective July 1, 2011, in accordance with Section 499.0121(14), Florida Statutes, all controlled substance distributors meeting **both** of the following requirements were required to register with the department's Controlled Substance Reporting system ("CSR") and submit monthly controlled substance distribution reports:

1. Distributes or may distribute from time to time **any** controlled substance (Schedules II through V, inclusive, per Section 893.03, Florida Statutes) in or into Florida; **and**

2. Permitted (or required to be permitted) as one of the following:

   - Prescription Drug Wholesale Distributor,
   - Out-of-State Prescription Drug Wholesale Distributor,
   - Retail Pharmacy Drug Wholesale Distributor,
   - Prescription Drug Manufacturer,
   - Nonresident Prescription Drug Manufacturer, or
   - Prescription Drug Repackager.

Our records indicate that many non-registered, non-reporting permittees also hold U.S. Drug Enforcement Administration registrations for their permitted establishment(s), and therefore **may** be out of compliance. **Affected companies must still submit a report if no controlled distributions occurred during the particular month.**

We hope that the industry will invest in the department's commitment to the statewide and national struggle against controlled substance diversion and abuse. Florida's CSR cannot achieve its full potential, however, without substantially greater industry participation. All affected companies are strongly encouraged to achieve compliance as soon as possible.

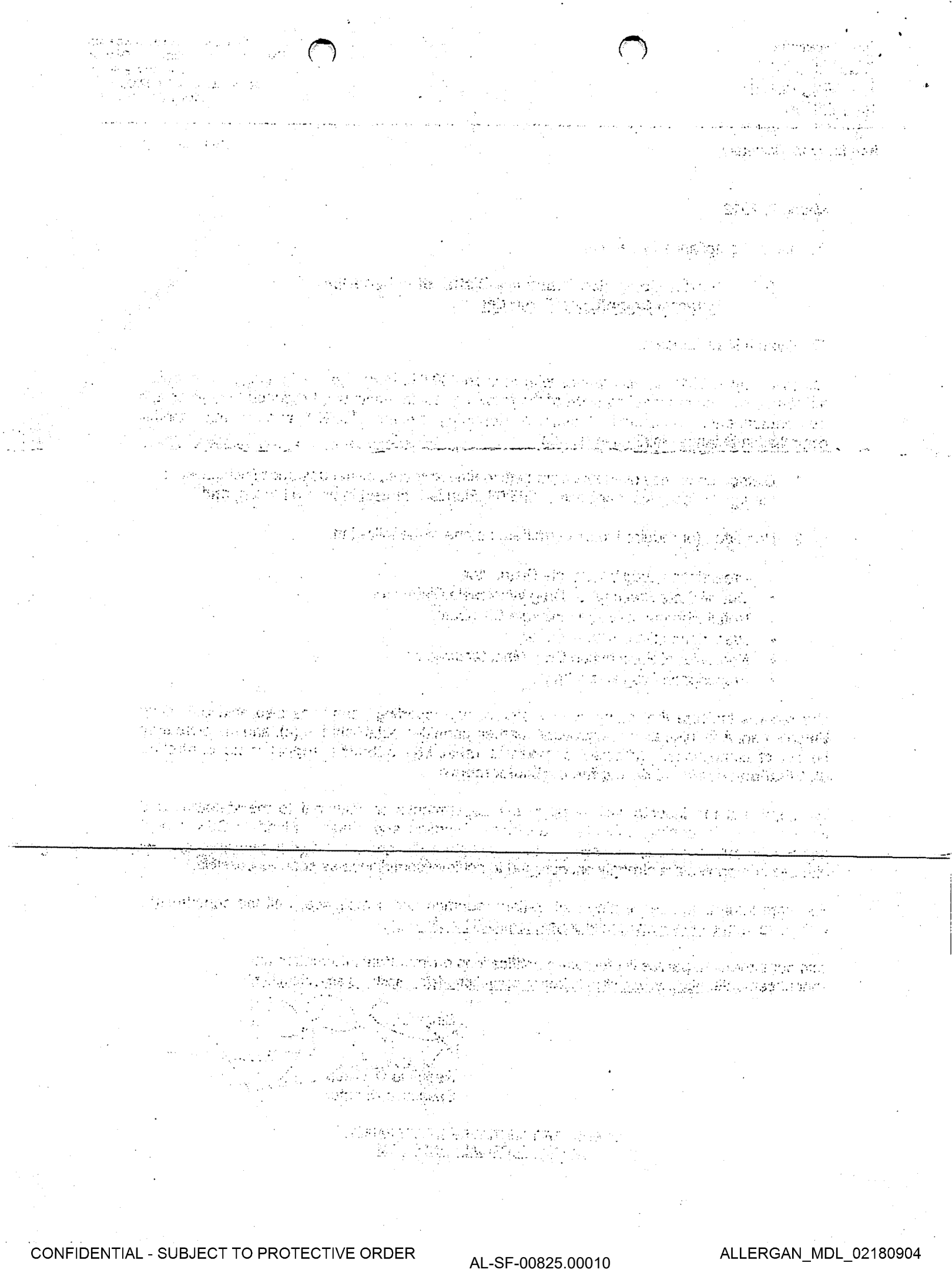
For more information concerning registration, reporting and compliance, visit the department's web page: https://www.myfloridalicense.com/CSR/login.aspx.

Join our interested parties list for future notifications on important information and announcements: http://www.myfloridalicense.com/dbpr/ddc/subscribe_alertsystem.html

Sincerely,

Reginald D. Dixon
Executive Director

LICENSE EFFICIENTLY. REGULATE FAIRLY.
WWW.MYFLORIDALICENSE.COM



actavis
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VIA UPS COURIER

August 28, 2012

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399

RE: License No. 261153

Dear Colleague:

Enclosed please find our completed Non-Resident Prescription Drug Manufacturer renewal application along with our check No. 319995 for $1,000 to cover the fee.

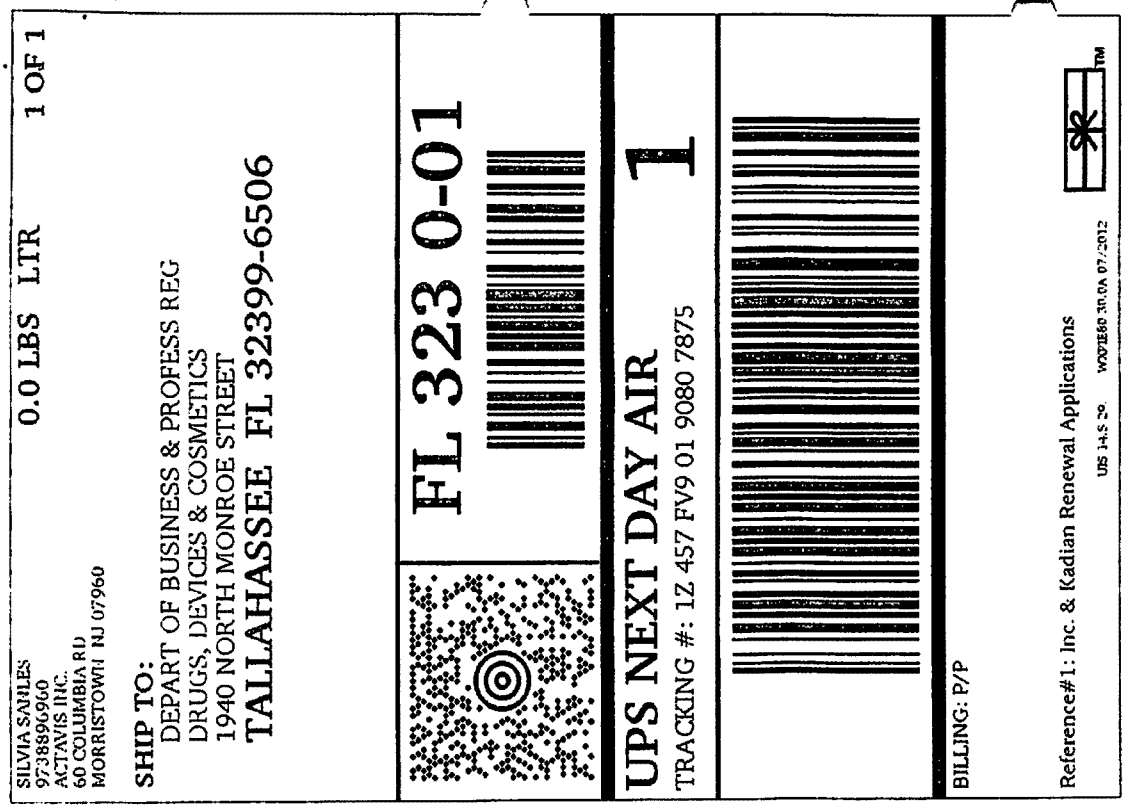
If you have any questions or require any additional information, please contact me at 973-889-6960.

Sincerely yours,
ACTAVIS KADIAN LLC

Silvia Sanlés
Supervisor, Regulatory Affairs

SS
Encls.

Actavis Inc. | 60 Columbia Rd., Bldg. B Morristown, NJ 07960 | t (973) 993-4501 | www.actavis.com



Florida Department of Business and Professional Regulation
Drugs, Devices, and Cosmetics
Application for Permit Renewal Under Chapter 499, F.S.

This application form provides information as required by the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes

Non-resident Prescription Drug Manufacturer Permit # 261154 expires September 30, 2012.

The fee of $1000.00 and the renewal notice must be postmarked on or before September 30, 2012 Renewal Notices postmarked on or after October 01, 2012 require renewal and delinquent fees of $1100.00

DEPARTMENT USE ONLY

1. CURRENT MAILING ADDRESS:
This address will be used for all correspondence from the Department

ACTAVIS INC.
60 COLUMBIA RD
BLDG- B
MORRISTOWN, NJ 07960

2. CURRENT PERMIT AND PHYSICAL ADDRESS:
This address will be printed on your license and posted on the Internet.

ACTAVIS INC.
60 COLUMBIA RD
BLDG- B
MORRISTOWN, NJ 07960

3. CONTACT IN CASE OF EMERGENCY:
Name :

Address :

Telephone Number :

☐ Above emergency contact information has been changed from your last application. (Provide correct emergency information.)

Christopher Young - 29 Stag Place

Lincroft (City) NJ (State) 07738 (ZIP) 732-530-0874 (Phone)

4. DO YOU HAVE MULTIPLE MANUFACTURING PERMITS/LICENSES IN THE SAME BUSINESS NAME AT THE SAME BUSINESS ADDRESS?

☐ Yes ☑ No

5. IF THERE HAS BEEN A CHANGE IN OWNERSHIP, THIS PERMIT CANNOT BE RENEWED. A NEW PERMIT IS REQUIRED.

Provide correct information if any change has occurred in the company name, mailing address, physical address, telephone number or operating hours.

☑ There have been no changes to the owners, partners or corporate officers.

OR

☐ There has been a change in the partners or corporate officers. (Attach current information: names, positions & dates of birth.)

6. HAVE CONDITIONS OR PRACTICES CHANGED THAT WOULD MAKE IT INELIGIBLE TO RENEW THIS PERMIT?

☐ Yes ☑ No

SINCE YOUR PREVIOUS APPLICATION WAS SUBMITTED, HAS THE APPLICANT, OWNER(S), MANAGER(S)-IN-CHARGE, ANY OFFICERS, AND/OR ANY EMPLOYEES:

Been found guilty (regardless of adjudication) or pled nolo contendere in a court in Florida or any other jurisdiction of a violation of law that directly relates to a drug, device, or cosmetic?	☐ Yes	☑ No
Been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?	☐ Yes	☑ No
Been convicted of any felony under a federal, state, or local law?	☐ Yes	☑ No
Had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?	☐ Yes	☑ No
Been denied a permit or license related to an activity regulated under Chapter 499, F.S., in any state?	☐ Yes	☑ No

ANY "YES" RESPONSE MUST BE DISCUSSED ON AN ATTACHED SHEET.

7. COMPANIES LOCATED OUTSIDE THE STATE OF FLORIDA PROVIDE THE FOLLOWING:

Current valid license number in resident state: 5003899 Expires: 1/31/13 (Attach a copy of the current permit.)

8. OTHER INFORMATION:

By submitting the appropriate renewal fees to the Department, I certify compliance with all requirements for renewal. I am responsible for knowing these requirements as set forth in the laws and rules that govern my profession.

File Number: 6511

Profession Code: 3326

DBPR-DDC1 , 9/11
Rule 64F-12.015, F.A.C.

Renewal form continued on back of page...

9. CHANGE OF PHYSICAL ADDRESS (THIS ADDRESS CAN NOT BE A POST OFFICE BOX):

Change in the Physical Address of a permit issued to an establishment located outside of Florida requires an additional fee of **$25.00** for each permit. Other permittees must pay an applicable Change of Address fee as required by Rule 64F-12.018(4), Fla. Admin Code which will be **$100.00** for one permit plus **$25.00** for each additional permit. A Change of Address form may be obtained by visiting: http://www.myfloridalicense.com.

10. THERE IS ONLY ONE RENEWAL METHOD AVAILABLE:

US Mail: Mail completed form and fee payable to **Department of Business and Professional Regulation** to the following address:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399-1047

11. CHECKLIST FOR MAILING RENEWAL FORM:

If mailing your renewal form, use the checklist below as a guide for enclosing all the required items to ensure a smooth renewal. If renewing by mail, allow 2 - 4 weeks processing time.

- [✓] **Renewal notice**
- [✓] **Cashier's Check or Money Order written to Department of Business and Professional Regulation**
- [✓] **If you checked a change in the partner or corporate officers in item # 5, please attach current information.**
- [✓] **Provide correct emergency contact residence address and residence telephone number.**
- [ ] **If you are a company located outside the State of Florida, attach a copy of the current resident state permit.**
- [✓] **Mail to: Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahasse, FL 32399-1047**

12. AFFIDAVIT (must be completed):

I DO SOLEMNLY SWEAR OR AFFIRM THAT THE INFORMATION SUBMITTED TO THE DEPARTMENT ON THIS APPLICATION AND ANY ATTACHMENTS THERETO ARE TRUE AND CORRECT.

Signature of Owner or Corporate Officer	Title	Date
[signature]	VP, Regulatory & Medical Affairs	8/21/12

If signed by someone other than an owner or officer, you must submit a letter of delegation for the signer to bind the applicant.

NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0706383

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

220 HAFNARF JORDUR REYKJAVIKURVEGI, IC 076-78-
60 COLUMBIA RD - BLDG B MORRISTOWN,NJ 07960-
47 BRUNSWICK AVE EDISON, NJ 08817-

Reg. No.
5003899

ACTAVIS GROUP, HF (ICELAND)
ACTAVIS INC
ATTN: SILVIA SANLAR
60 COLUMBIA RD - BLDG B
MORRISTOWN, NJ 07960-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2013

Establishment Copy

52150 DEPARTMENT OF BUSINESS & 319996

Invoice	Inv Date	Remarks	Net Amount
CHRQ08212012	08/21/12		1,000.00
			1,000.00

200 ELMORA AVE.
ELIZABETH, NJ 07207

CHECK NUMBER: 319996 08/22/12

Wells Fargo

USD ********1,000.00

One Thousand Dollars And No Cents

PAY TO THE ORDER OF:

DEPARTMENT OF BUSINESS &
PROFESSIONAL REGULATION
1940 NORTH MONROE STREET
TALLAHASSEE, FL 32399
UNITED STATES

Stephen Gallagher
AUTHORIZED SIGNATURE

⑈319996⑈ ⑆031100225⑆ 2079951076361⑈

52150 DEPARTMENT OF BUSINESS & 319996

Invoice	Inv Date	Remarks	Net Amount
CHRQ08212012	08/21/12		1,000.00
			1,000.00

ACTAVIS INC. CHECK REQUEST

Checks to be issued on Friday

Make Check Payable to:	
Name	Department of Business and Professional Regulation
Address	1940 North Monroe Street
City	Tallahassee
State, Zip	FL, 32399
Phone	850-245-4292

Amount -$	1000.00
Dept. and Cacti or Capex No.	98-35575-705

Reason Explain in Detail	Florida Renewal Rx Drugs & CDS application for Actavis Kadian LLC See attached
SPECIAL HANDLING INSTRUCTIONS	Please return to Silvia Sanles/Morristown

Originated By:	SILVIA SANLES
	Signature:
	Date: 8/21/12 Ext.: 1256960

Approved By:	TERRI NATALINE
	Signature:
	Date: 8/21/12 Ext.: 1202317

Approved By:	
Finance Review	Signature:
	Date: Ext.

Please attach all supporting documents. Invoices, Quotes, Proof of Delivery, etc.

2013

Legal met with Reginald Dixon and FL DBPR in early 2013 to discuss issues at all US sites concerning ownership change applications that were submitted in late 2012. It was discussed and decided that the Actavis Legacy sites did not require an ownership change due to the Actavis group ownership did not change. So no further action was required on our part.

John LaRocca and Nancy Baran attended the meeting in FL.

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VIA UPS OVERNIGHT

February 19, 2013

Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
Attn: Mary Grayson, Regulatory Specialist II
1940 North Monroe Street
Tallahassee, FL 32399

RE: Actavis LLC
Actavis South Atlantic LLC
Actavis Elizabeth LLC
Actavis Mid Atlantic LLC
Actavis South Atlantic LLC
Actavis Manufacturing Private Limited

Dear Colleague:

Reference is made to our change of ownership applications submitted on November 9, 2012. Enclosed please find the amended sections of our pending Resident and Non Resident Prescription Drug Manufacturing applications for the above-mentioned entities.

Please note that on January 1, 2013, Actavis Inc., located at 60 Columbia Road, Bldg. B, Morristown, NJ, was converted to an LLC. The new company name is **Actavis LLC** (attached are the documents for your review) and the EIN # 20-0269345 has not changed.

In addition, on January 24, 2013, Watson Pharmaceuticals, Inc., Actavis' parent company changed their name to **Actavis, Inc**. Attached are the documents for your review.

We are committed to keeping you informed about the integration progresses and we expect a smooth transition due to our extensive integration planning.

If you have any questions or require any additional information, please contact me by phone at 973-889-6960 or by e-mail at ssanles@actavis.com.

Sincerely,
ACTAVIS

Silvia Sanlés
Supervisor, Regulatory Affairs

Encls.

Actavis Regulatory Affairs Department | 200 Elmora Avenue Elizabeth, NJ 07207 | t 908 659 2527 f 908 659 2250 | RegulatoryAffairsUS@actavis.com

Silvia Sanles

From: UPS Quantum View <auto-notify@ups.com>
Sent: Wednesday, February 20, 2013 10:24 AM
To: Silvia Sanles
Subject: UPS Delivery Notification, Tracking Number 1Z457FV90193463526

UPS My Choice® can help you avoid missed home deliveries.

Learn More

***Do not reply to this e-mail. UPS and Actavis Morristown will not receive your reply.

At the request of Actavis Morristown, this notice is to confirm that the following shipment has been delivered.

Important Delivery Information

Tracking Number: 1Z457FV90193463526
Delivery Date / Time: 20-February-2013 / 9:59 AM

Delivery Location: INSIDE DELIVERY
Signed by: MILTON

Shipment Detail

Ship To:
Mary Grayson, Regulatory Specialist
Dept. of Business & Profes Reg
1940 N MONROE ST
TALLAHASSEE
FL
32399
US

Number of Packages: 1
UPS Service: NEXT DAY AIR
Weight: 1.0 LBS

For more information on UPS's privacy practices, refer to the UPS Privacy Policy.
Please do not reply directly to this e-mail. UPS will not receive any reply message.
For questions or comments, visit Contact UPS.

Privacy Notice
Contact UPS

AMMENDMENT TO PENDING NON-RESIDENT PRESCRIPTION DRUG MANUFACTURER APPLICATION

ACTAVIS KADIAN LLC

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General).
Name: CT (Corporation System) **Address:** 1200 South Pine Island Road Plantation FL 33324

List the name, position/title, date of birth and percentage of ownership, if applicable, for the applicant's owners, partners, members, managers, and corporate officers/directors.

Name	Position/Title	Date of Birth	% of Ownership
Paul M. Bisaro	President & CEO	6/01/1961	0 %
[redacted]	CFO - Global	11/04/1958	0 %
[redacted]	CCC - Global	12/20/1964	0 %
[redacted]	VP & Assistant Secretary	07/16/1964	0 %

List all trade or business names used by the applicant. Use additional sheet(s) if necessary.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership. Please note: A permit issued pursuant to this application is only valid for the applicant's name and applicant's address.)	☑ Yes ☐ No

Parent Company Name	% of Ownership
Actavis LLC	100 %
Actavis LLC is 100% owned by Actavis Inc (formerly Watson Pharmaceuticals Inc)	

Does the applicant, the applicant's parent, sister or subsidiary companies, provide diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care? If so, please list all company/companies below. (Use additional sheet(s) if necessary).	☐ Yes ☐ No

Section IV – Background Questions

BACKGROUND QUESTIONS			
1.	☐ Yes If yes, explain in detail in Section V	☑ No	Has the applicant or any "affiliated party" (defined below) been found guilty (regardless of adjudication) or pled nolo contendere in any jurisdiction of a violation of law that directly relates to a drug, device or cosmetic?
2.	☐ Yes	☑ No	Has the applicant or any affiliated party been fined or disciplined by a

Section VI – Other Permits or Licenses

PERMITS OR LICENSES				
1.	Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If yes, provide the name in which the permit is issued, the permit type, & permit number in the spaces provided below.)			☐ Yes ☑ No
1a.	Permit/License Name	Permit/License Type	Permit/License Number	
2.	Is the applicant licensed in any other state as a manufacturer, repackager, or wholesaler of prescription drugs? (If yes, list all states where licensed, including the license numbers and expiration date in the spaces provided below. Use separate sheet of paper if needed.) Submitting original application 11/9/2012			☑ Yes ☐ No
2a.	State	Permit/License Number/Type	Permit/License Number/Type	Expiration Date
3.	Does the location for which you are applying sell prescription drugs into Florida? (If no, provide the name and address from which the drugs are sold into Florida in the spaces provided below. Use additional sheets if needed.)			☑ Yes ☐ No
3a.	Name	Physical Address	Florida Permit/License Number	
4.	Does the location for which you are applying ship prescription drugs into Florida? (If no, provide the name and address of all locations that ship prescription drugs into Florida on your behalf in the spaces provided below. Use additional sheets if needed.)			☑ Yes ☐ No
4a.	Name	Physical Address	Florida Permit/License Number	
	[redacted]			

Section VII – Prescription Drug Manufacturing Activity

MANUFACTURING ACTIVITIES		
Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance.		
☐ Manufacturers	☐ Wholesalers	☐ Pharmacies
☐ Hospitals	☐ Practitioners	☐ Clinics
☐ Veterinarians		

Application for Licensure as a Non-Resident Prescription Drug Manufacturer
Actavis Kadian LLC

Section VI – Other Permits or Licenses

Question 4a: Provide the name and address of all locations that ship prescription drugs into Florida on your behalf in the spaces provided below.

Watson Pharma, Inc.
605 Tri-State Parkway
Gurnee, IL 60031
847-377-5500 – phone
847-377-5501 – fax
Edward Grover – contact
Florida License #: 2600276

UPS Supply Chain Solutions Inc.
1860 Outer Loop Road
Louisville, KY 40219
1-502-96-7393 – phone
Todd Dutton – contact
actavis@ups.com
Florida License #:021

actavis
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VIA UPS COURIER

November 9, 2012

State of Florida
Dept. of Business & Professional Regulation
Division of Drugs, Devices and Cosmetics
1940 North Monroe Street
Tallahassee, Florida 32399

To Whom It May Concern:

Attached please find an application for a non-resident prescription drug manufacturer for Actavis Kadian LLC, located at 60 Columbia Road, Bldg. B, Morristown, New Jersey. Our current permit number is 261153.

Pursuant to the Florida statutes under the Florida Drug and Cosmetic Act, 499.012-9(6)(b)1, we are submitting a new application and advising you that Actavis Inc. and all its subsidiaries were acquired by Watson Pharmaceuticals, Inc. on October 31, 2012.

Should you have any questions or require additional information, please feel free to contact me at 973-889-6960 or by email at ssanles@actavis.com.

Thank you.

Sincerely,
Actavis Kadian LLC

Silvia Sanles
Supervisor, Regulatory Affairs

enclosures

Actavis Regulatory Affairs Department | 60 Columbia Road, Bldg B Morristown, NJ 07960 | t 908 659 2527 f 908 659 2250 | www.actavis.com

8-K 1 d432556d8k.htm FORM 8-K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
October 31, 2012

WATSON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	001-13305	95-3872914
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Morris Corporate Center III 400 Interpace Parkway Parsippany, New Jersey	07054
(Address of Principal Executive Offices)	(Zip Code)

(862) 261-7000
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On October 31, 2012, Watson Pharma S.à r.l. (the "Purchaser"), a company incorporated in Luxembourg and wholly-owned subsidiary of Watson Pharmaceuticals, Inc., a Nevada corporation ("Watson"), Nitrogen DS Limited, a company incorporated in the British Virgin Islands ("Nitrogen"), Landsbanki Islands hf., a company incorporated in Iceland ("Landsbanki") and Deutsche Bank AG, London Branch, a branch of a company incorporated under the laws of the Federal Republic of Germany ("DB"), entered into an amendment (the "Purchase Agreement Amendment") to that certain Sale and Purchase Agreement (the "Purchase Agreement"), dated as of April 25, 2012, by and among, Watson, the Purchaser, Actavis Acquisition Debt S.à r.l., a company incorporated in Luxembourg (the "Vendor"), Nitrogen, Landsbanki, ALMC Eignarhaldsfélag ehf., a company incorporated in Iceland ("ALMC", together with Nitrogen and Landsbanki, the "Indirect Equity Holders"), ALMC hf., a company incorporated in Iceland, Argon Management S.à r.l., a company incorporated in Luxembourg, the Managers party thereto and DB (together with Landsbanki, the "Debt Holders" and the Debt Holders together with the Indirect Equity Holders and the Managers, the "Indirect Interest Holders") pursuant to which the parties amended certain provisions of the Purchase Agreement relating to the mechanics by which the novation of the Vendor's rights and obligations under the Purchase Agreement occurs, such that following completion of the acquisition of the Interests (as defined below) and the assumption of a payable ("Completion") and upon the Vendor's election, all of the rights and obligations of the Vendor under the Purchase Agreement shall be novated and ultimately transferred to Nitrogen, Landsbanki, DB and the Managers party to the Purchase Agreement, who shall then assume responsibility in pre-determined proportions for the performance of the Vendor's obligations (subject to the same limitations incumbent on the Vendor's obligations in the Purchase Agreement) (the "Novation").

The Purchase Agreement Amendment also provides that following the Novation, Landsbanki and DB may withdraw their respective proportions of monies paid into escrow accounts established at Completion to settle any liability for claims by the Purchaser in respect of their proportionate liability for completion account adjustments and breaches of the interim covenants or Vendor's warranties, such that the Purchaser may only seek recovery for their proportionate liability directly from Landsbanki and DB in the event of any such claims.

The foregoing description of the Purchase Agreement Amendment and Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full texts of the Purchase Agreement Amendment filed hereto as Exhibit 2.1 and the Purchase Agreement filed as Exhibit 2.1 to the current report filed on Form 8-K dated as of April 25, 2012, and incorporated herein by reference. The Purchase Agreement Amendment has been included to provide investors with information regarding its terms, however it is not intended to provide any other factual information about Watson, the Vendor, the Companies or the Indirect Interest Holders.

Item 2.01. Completion of Acquisition or Disposition of Assets.

On October 31, 2012, Watson and the Purchaser completed the acquisition (the "Acquisition") of (i) the entire issued share capital of Actavis, Inc., a Delaware corporation, Actavis Pharma Holding 4 ehf., a company incorporated in Iceland, and Actavis S.à r.l., a company incorporated in Luxembourg (collectively, the "Companies") and (ii) all the rights of the Vendor, in certain indebtedness of the Companies (the "Intra Group Debt" and, together with the shares of the Companies, the "Interests").

Pursuant to the terms of the Purchase Agreement, the Purchaser made a cash payment of €4.0 billion and paid €100 million of indebtedness of the Vendor in exchange for the Interests. In addition, certain Indirect Interest Holders received the potential right to receive contingent consideration payable in the form of up to 5.5 million newly issued shares of Common Stock, $0.0033 par value per share, of Watson ("Common Shares") based on the Companies' financial performance in 2012 as described in the Purchase Agreement.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

In connection with the completion of the Acquisition, and pursuant to and in accordance with the Fourth Amendment and Restatement of the 2001 Incentive Award Plan of Watson, effective as of May 4, 2007, as amended, the compensation committee of the Board of Directors approved a one-time grant of restricted Common Shares to members of the executive committee, as follows:

Sigurdur Olafsson	14,543 restricted Common Shares
Robert Stewart	14,543 restricted Common Shares
David Buchen	5,817 restricted Common Shares
R. Todd Joyce	5,817 restricted Common Shares
Charles Mayr	2,909 restricted Common Shares
Patrick Eagan	2,909 restricted Common Shares
G. Frederick Wilkinson	2,909 restricted Common Shares

Each of the grants shall become vested in full subject to such individual's continued employment by Watson on October 31, 2014.

Item 7.01. Regulation FD Disclosure.

Watson's news release announcing the completion of the Acquisition is furnished as Exhibit 99.1 to this Form 8-K.

In connection with the completion of the Acquisition of the Companies, Watson also announced its intent to adopt the brand name "Actavis" for its worldwide operations beginning in 2013 and the appointment of its Global Generics management team, including its U.S. and international businesses and R&D team. The news releases announcing the intended name change and the Global Generics management team are furnished as Exhibits 99.2 and 99.3 respectively to this Form 8-K.

The information in the news releases shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Exhibit
2.1	Deed of Modification and Withdrawal from Escrow Accounts, dated as of October 31, 2012, to the Sale and Purchase Agreement dated April 25, 2012, by and among Nitrogen DS Limited, Landsbanki Islands hf., ALMC Eignarhaldsfélag ehf., ALMC hf., Argon Management S.à r.l., the Managers party thereto, Deutsche Bank AG, London Branch, Actavis Acquisition Debt S.à r.l., Watson Pharma S.à r.l. and Watson Pharmaceuticals, Inc.
99.1	Press Release issued by Watson Pharmaceuticals, Inc. on October 31, 2012.
99.2	Press Release issued by Watson Pharmaceuticals, Inc. on October 31, 2012.
99.3	Press Release issued by Watson Pharmaceuticals, Inc. on October 31, 2012.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 31, 2012

WATSON PHARMACEUTICALS, INC.

By: /s/ David A. Buchen
Name: David A. Buchen, Esq.
Title: Chief Legal Officer – Global

EXHIBIT INDEX

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State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Non-Resident Prescription Drug Manufacturer
Form No.: DBPR-DDC-202

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. ***For additional information see the instructions at the beginning of this application.***

Section I- Application Type

CHECK ONE OF THE APPLICATION TYPES
☐ New Application [3326/1020]
☑ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3326/1020]
Current Permit Number 26115.3

Section II – Applicant Information

APPLICANT INFORMATION		
Federal Tax Identification Number:		
FULL LEGAL NAME		
Applicant's Full Legal Name: Actavis Kadian LLC.		
FICTITIOUS, TRADE OR BUSINESS NAME (applies only if different from full legal name)		
Full Fictitious, Trade or Business Name (sometimes "d/b/a" or "dba"): N/A Note: This name will appear on the permit and must be used on the applicant's operational documents for permitting activities. If the applicant intends to operate under a fictitious, trade or business name, provide the corresponding registration number from the Florida Secretary of State, Division of Corporations: N/A		
APPLICANT'S MAILING ADDRESS		
Street Address or P.O. Box: Actavis - Attn: Silvia Sanles 60 Columbia Rd, Bldg B		
City: Morristown	State: NJ	Zip Code (+4 optional): 07960
PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED (if different from mailing address)		
Street Address: Same as mailing address		
City:	State:	Zip Code (+4 optional):
County (if Florida address):	Country:	
E-Mail Address:	Phone Number:	Fax Number:

APPLICATION CONTACT

Whom should the department contact with questions regarding this application?

Last/Surname:	First:	Middle:	Suffix:
Sanles	Silvia		

Address: [illegible]

City:	State:	Zip Code (+4 optional):
Morristown	NJ	07960

Telephone Number:	Fax Number:
973-889-6960	973-993-4305

E-Mail Address: SSanles@actavis.com

EMERGENCY CONTACT -INFORMATION

Last/Surname:	First:	Middle:	Suffix:
Young	Christopher	C.	

Position/Title: VP US Operations

Home Street Address (must be different than establishment physical address):

29 Stag Place

City:	State:	Zip Code (+4 optional):
Lincroft	NJ	07738

Home Phone Number:	E-Mail Address:
732-530-0874	cyoung@actavis.com

OPERATING HOURS

List Operating Hours – minimum 10 total per week (M-F) between 8:00 a.m. and 5:00 p.m., Eastern Standard Time, and at least 2 consecutive hours on at least 1 day:

Mon	8:30 am/pm to 5:00 am/pm	Fri	8:30 am/pm to 5:00 am/pm
Tue	8:30 am/pm to 5:00 am/pm	Sat	:____ am/pm to :____ am/pm
Wed	8:30 am/pm to 5:00 am/pm	Sun	:____ am/pm to :____ am/pm
Thu	8:30 am/pm to 5:00 am/pm		

Section III – Ownership Information

TYPE OF OWNERSHIP

☐ Publicly Held Corporation	☐ Closely Held Corporation	☑ Limited Liability Company
☐ Charitable Organization—501(c)(3)	☐ Sole Proprietorship	☐ Government
☐ Partnership – General	☐ Professional Corporation or Association	☐ Professional Limited Liability Company
☐ Partnership – Other, Including Limited Liability Partnership and Limited Partnership	☐ Other:_____	

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

State: Delaware

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General).
Name: United Corporate Services
Address: [illegible]

List the name, position/title, date of birth and percentage of ownership, if applicable, for the applicant's owners, partners, members, managers, and corporate officers/directors.

Name	Position/Title	Date of Birth	% of Ownership

List all trade or business names used by the applicant. Use additional sheet(s) if necessary.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership. Please note: A permit issued pursuant to this application is only valid for the applicant's name and applicant's address.)	☑ Yes ☐ No

Parent Company Name	% of Ownership
*Actavis Inc	100
*Actavis Inc a Delaware corporation is 100% owned by Watson Pharmaceuticals Inc. a Nevada corporation.	

Does the applicant, the applicant's parent, sister or subsidiary companies, provide diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care? If so, please list all company/companies below. (Use additional sheet(s) if necessary).	☐ Yes ☑ No

Section IV – Background Questions

BACKGROUND QUESTIONS			
1.	☐ Yes If yes, explain in detail in Section V	☑ No	Has the applicant or any "affiliated party" (defined below) been found guilty (regardless of adjudication) or pled nolo contendere in any jurisdiction of a violation of law that directly relates to a drug, device or cosmetic?
2.	☐ Yes	☑ No	Has the applicant or any affiliated party been fined or disciplined by a

	If yes, explain in detail in Section V		regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?
3.	☐ Yes If yes, explain in detail in Section V	☑ No	Has the applicant or any affiliated party been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?
4	☐ Yes If yes, explain in detail in Section V	☑ No	Has the applicant or any affiliated party been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, 893, F.S.?
5	☐ Yes If yes, explain in detail in Section V	☑ No	Has the applicant or any affiliated party had any current or previous permit or license suspended or revoked which was issued by a federal, state or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?
6	☐ Yes If yes, explain in detail in Section V	☑ No	Has the applicant or any affiliated party ever held a permit issued under Chapter 499, F.S. in a different name than the applicant's name? If yes, provide the names in which each permit was issued and at what address.)

The term "affiliated party" includes all of the following that may apply: the applicant's (i) directors, officers, trustees, partners, or committee members; (ii) any person who manages, controls or oversees the applicant's operations (does not have to be an employee), including the establishment manager and the next four (4) highest ranking employees responsible for prescription drug wholesale operations; and (iii) the five (5) individuals (natural persons) who own at least 5% of the applicant's stock ownership interest.

If you answered "YES" to any questions in Section IV, provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

Section V – Explanation(s) for "Yes" response(s) to background question(s)

EXPLANATION

Section VI – Other Permits or Licenses

PERMITS OR LICENSES				
1.	Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If yes, provide the name in which the permit is issued, the permit type, & permit number in the spaces provided below.)			☐ Yes ☑ No
1a.	Permit/License Name	Permit/License Type	Permit/License Number	
2.	Is the applicant licensed in any other state as a manufacturer, repackager, or wholesaler of prescription drugs? (If yes, list all states where licensed, including the license numbers and expiration date in the spaces provided below. Use separate sheet of paper if needed.) See Attached			☑ Yes ☐ No
2a.	State	Permit/License Number/Type	Permit/License Number/Type	Expiration Date
3.	Does the location for which you are applying sell prescription drugs into Florida? (If no, provide the name and address from which the drugs are sold into Florida in the spaces provided below. Use additional sheets if needed.)			☑ Yes ☐ No
3a.	Name	Physical Address	Florida Permit/License Number	
4.	Does the location for which you are applying ship prescription drugs into Florida? (If no, provide the name and address of all locations that ship prescription drugs into Florida on your behalf in the spaces provided below. Use additional sheets if needed.)			☑ Yes ☐ No
4a.	Name	Physical Address	Florida Permit/License Number	

Section VII – Prescription Drug Manufacturing Activity

MANUFACTURING ACTIVITIES		
Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance.		
☐ Manufacturers	☑ Wholesalers	☐ Pharmacies
☐ Hospitals	☐ Practitioners	☐ Clinics
☐ Veterinarians	Distributors, Drug Chain Warehouses/Distribution Centers	

☑ Other (explain) GPOs, Repackers, Mail Order Accounts, Nursing Homes & Retail Managed Care Organizations & Buying Groups

Identify the types of products the applicant will manufacture or distribute under this permit.

☐ Human Prescription Drugs
☐ Solid Dose
☐ Liquids (Oral)
☐ Injectables
☐ Topical
☐ Dental
☐ Ophthalmic
☐ Compressed Medical Gases

☐ Veterinary Prescription Drugs

☐ Repackage – From Bulk
☐ Repackage – From Stock

☐ Refrigerated (Human, Veterinary, API or Otherwise)
☐ Frozen (Human, Veterinary, API or Otherwise)

☐ Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers):
☐ Manufacturers ☐ Pharmacies for Compounding ☐ Other explain_____

Controlled Substances: Provide your DEA Number: Not Required - Corporate office only

Check Schedules: ☐ Sch II ☐ Sch III ☐ Sch IV ☐ Sch V

Identify type of operation.

☐ Contract Manufacturer	☑ ~~Own~~ Label Manufacturer Private	☐ Limited Manufacturing Operations (Sterilizing, Encapsulating, etc.)

Provide your FDA establishment registration number.

FDA Establishment Registration Number: Not Required for a Private Label Distributor

Provide all National Drug Codes (NDCs) for all drug listings manufactured or distributed from the establishment. (Provide NDCs and drug listing on a separate sheet.)

NDCs and drug listings: 46987

1.	Does your company sell and/or distribute only FDA approved drugs? (If no, explain on a separate sheet of paper.)	☑ Yes ☐ No
2.	Do you manufacture a prescription drug as a finished product? (If no, explain on a separate sheet providing accurate details.) Corporate Office Only	☐ Yes ☑ No
3.	Will you distribute prescription drugs, including any active pharmaceutical ingredient (API), used or intended for use in the manufacture of a prescription drug from the establishment? (For assistance in determining the definition of "distribute" see Section 499.003(17), Florida Statutes.)	☐ Yes ☑ No
4.	Do you intend to manufacture or distribute prescription drug samples? (If yes, a Complimentary Drug Distributor permit is required.)	☐ Yes ☑ No
5.	Do you understand that a repackager of prescription drugs is not considered a manufacturer for the purpose of this permit and that an Out-Of-State Prescription Drug Wholesale Distributor permit is required to wholesale repackaged drugs into Florida?	☑ Yes ☐ No
6.	Do you repackage prescription drugs?	☐ Yes ☑ No
7.	Do you understand that this permit only authorizes the distribution of prescription drugs made by you, or your client, and that if you sell and/or distribute a prescription drug made by another, you will be required to obtain	☑ Yes ☐ No

ACTAVIS KADIAN LLC
Current Permit # 261153
Application for Permit as a Non-Resident Prescription Drug Manufacturer

Section VII – Prescription Drug Manufacturing Activity

Provide all National Drug Codes (NDCs) for all drug listings manufactured or distributed from the establishment.

46987-322-11
46987-323-11
46987-324-11
46987-325-11
46987-326-11
46987-327-11
46987-328-11
46987-329-11
46987-330-11
46987-377-11
46987-410-11
46987-412-11

HIGHLIGHTS OF PRESCRIBING INFORMATION

KADIAN® (morphine sulfate) Extended-Release Capsules, for oral use, CII

These highlights do not include all the information needed to use Kadian safely and effectively. See full prescribing information for Kadian.

Kadian (morphine sulfate) CAPSULE, EXTENDED RELEASE for ORAL use.

Initial U.S. Approval: 1941

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

See full prescribing information for complete boxed warning.

- **KADIAN contains pellets of morphine sulfate, a Schedule II controlled substance. Monitor for signs of misuse, abuse, and addiction during KADIAN therapy. (5.1, 9)**
- **Fatal respiratory depression may occur, with highest risk at initiation and with dose increases. Instruct patients on proper administration of KADIAN capsules to reduce the risk. (5.2)**
- **Accidental ingestion of KADIAN can result in fatal overdose of morphine, especially in children. (5.3)**

RECENT MAJOR CHANGES

Boxed Warning	07/2012
Indications and Usage (1)	07/2012
Dosage and Administration (2)	07/2012
Contraindications (4)	07/2012
Warnings and Precautions (5)	07/2012

INDICATIONS AND USAGE

KADIAN is an opioid agonist product indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time (1)

Limitations of Use

- KADIAN is not for use:
- As an as-needed (prn) analgesic (1)
- For pain that is mild or not expected to persist for an extended period of time (1)
- For acute pain (1)
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (1)
- KADIAN 100 mg, 130 mg, 150 mg, and 200 mg capsules are only for patients in whom tolerance to an opioid of comparable potency is established. (1)

DOSAGE AND ADMINISTRATION

Individualize dosing based on patient's prior analgesic treatment experience, and titrate as needed to provide adequate analgesia and minimize adverse reactions. (2.1, 2.2)

Instruct patients to swallow KADIAN capsules intact, or to sprinkle the capsule contents on applesauce and immediately swallow. (2.4)

Do not abruptly discontinue KADIAN in a physically dependent patient. (2.5, 5.11)

DOSAGE FORMS AND STRENGTHS

Capsules: 10 mg, 20 mg , 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, 200 mg (3)

CONTRAINDICATIONS

- Significant respiratory depression (4)
- Acute or severe bronchial asthma (4)
- Known or suspected paralytic ileus (4)
- Hypersensitivity to morphine (4)

WARNINGS AND PRECAUTIONS

- Elderly, cachectic, and debilitated patients and patients with chronic pulmonary disease: Monitor closely because of increased risk of respiratory depression. (5.4, 5.5)
- Interaction with CNS depressants: Consider dose reduction of one or both drugs because of additive effects. (5.6, 7.2)
- Hypotensive effect: Monitor during dose initiation and titration (5.7)
- Patients with head injury or increased intracranial pressure: Monitor for sedation and respiratory depression and avoid use of KADIAN in patients with impaired consciousness or coma susceptible to intracranial effects of CO_2 retention. (5.8)

ADVERSE REACTIONS

Most common adverse reactions (>10%): constipation, nausea, and somnolence. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Actavis Kadian LLC at 1-888-496-3082 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

To report SUSPECTED ADVERSE REACTIONS, contact at or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

- Mixed agonist/antagonist opioid analgesics: Avoid use with KADIAN because they may reduce analgesic effect of KADIAN or precipitate withdrawal symptoms. (5.11, 7.3)
- Muscle relaxants: Avoid use with KADIAN because of increased risk of respiratory depression. (7.4)
- Monoamine oxidase inhibitors (MAOIs): Avoid KADIAN in patients taking MAOIs or within 14 days of stopping such treatment. (7.5)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm. (8.1)
- Nursing mothers: Morphine has been detected in human milk. Closely monitor infants of nursing women receiving KADIAN. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and the FDA-approved Medication Guide

Revised: 07/2012

FULL PRESCRIBING INFORMATION: CONTENTS *

*** Sections or subsections omitted from the full prescribing information are not listed**

FULL PRESCRIBING INFORMATION

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, AND ACCIDENTAL EXPOSURE

Abuse Potential

KADIAN contains morphine, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit [see Warnings and Precautions (5.1)]. Assess each patient's risk for opioid abuse or addiction prior to prescribing KADIAN. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving KADIAN for signs of misuse, abuse, and addiction during treatment [see Drug Abuse and Dependence (9)].

Life-threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of KADIAN, even when the drug has been used as recommended and not misused or abused [see Warnings and Precautions (5.2)]. Proper dosing and titration are essential and KADIAN should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of KADIAN or following a dose increase. Instruct patients to swallow KADIAN capsules whole or to sprinkle the contents of the capsule on applesauce and swallow without chewing. Crushing, dissolving, or chewing the pellets within the capsule can cause rapid release and absorption of a potentially fatal dose of morphine.

Accidental Exposure

Accidental consumption of KADIAN, especially in children, can result in a fatal overdose of morphine [see Warnings and Precautions (5.3)].

1 INDICATIONS & USAGE

KADIAN is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use

KADIAN is not for use:

- As an as-needed (prn) analgesic

- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

KADIAN 100 mg, 130 mg, 150 mg, and 200 mg capsules are only for patients in whom tolerance to an opioid of comparable potency is established. Patients considered opioid-tolerant are those taking at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid for a week or longer.

2 DOSAGE & ADMINISTRATION

2.1 Initial Dosing

Initiate the dosing regimen for each patient individually, taking into account the patient's prior analgesic treatment experience. Monitor patients closely for respiratory depression, especially within the first 24 to 72 hours of initiating therapy with KADIAN [see Warnings and Precautions (5.2)].

Consider the following factors when selecting an initial dose of KADIAN:

- Total daily dose, potency, and any prior opioid the patient has been taking previously;
- Reliability of the relative potency estimate used to calculate the equivalent dose of morphine needed (Note: potency estimates may vary with the route of administration);
- Patient's degree of opioid experience and opioid tolerance;
- General condition and medical status of the patient;
- Concurrent medication;
- Type and severity of the patient's pain.

KADIAN is administered at a frequency of either once daily (every 24 hours) or twice daily (every 12 hours).

Use of KADIAN as the First Opioid Analgesic

There has been no evaluation of KADIAN as an initial opioid analgesic in the management of pain. Because it may be more difficult to titrate a patient to adequate analgesia using an extended-release morphine, begin treatment using an immediate-release morphine formulation and then convert patients to KADIAN as described below.

Conversion from Other Oral Morphine Formulations to KADIAN

Patients receiving other oral morphine formulations may be converted to KADIAN by administering one-half of the patient's total daily oral morphine dose as KADIAN twice daily or by administering the total daily oral morphine dose as KADIAN once daily. There are no data to support the efficacy or safety of prescribing KADIAN more frequently than every 12 hours.

KADIAN is not bioequivalent to other extended-release morphine preparations. Conversion from KADIAN to the same total daily dose of another extended-release morphine product may lead to either excessive sedation at peak or inadequate analgesia at trough. Therefore, monitor patients closely when initiating KADIAN therapy and adjust the dosage of KADIAN as needed.

Conversion from Parenteral Morphine, or Other Opioids to KADIAN

While there are useful tables of oral and parenteral equivalents, there is substantial inter-patient variation in the relative potency of different opioid drugs and formulations. As such, it is safer to underestimate a patient's 24-hour oral morphine requirement and provide rescue medication (e.g. immediate-release morphine) than to overestimate and manage an adverse reaction. Consider the following general points:

Parenteral to Oral Morphine Ratio: Between 2 mg and 6 mg of oral morphine may be required to provide analgesia equivalent to 1 mg of parenteral morphine. Typically, a dose of oral morphine that is three times the daily parenteral morphine requirement is sufficient.

Other Oral or Parenteral Opioids to Oral Morphine Sulfate: Specific recommendations are not available because of a lack of systematic evidence for these types of analgesic substitutions. Published relative potency data are available, but such ratios are approximations. In general, begin with half of the estimated daily morphine requirement as the initial dose, managing inadequate analgesia by supplementation with immediate-release morphine.

The first dose of KADIAN may be taken with the last dose of any immediate-release opioid medication due to the extended-release characteristics of the KADIAN formulation.

2.2 Titration and Maintenance of Therapy

Individually titrate KADIAN to a dose that provides adequate analgesia and minimizes adverse reactions at a frequency of either once or twice daily. Continually reevaluate patients receiving KADIAN to assess the maintenance of pain control and the relative incidence of adverse reactions. During chronic therapy, especially for non-cancer-related pain (or pain associated with other terminal illnesses), periodically reassess the continued need for the use of opioid analgesics.

If the level of pain increases, attempt to identify the source of increased pain, while adjusting the KADIAN dose to decrease the level of pain. Because steady-state plasma concentrations are approximated within 24 to 36 hours, KADIAN dosage adjustments may be done every 1 to 2 days. Patients who experience breakthrough pain may require dosage adjustment or rescue medication with a small dose of an immediate-release medication. In patients experiencing inadequate analgesia with once daily dosing of KADIAN, consider a twice daily regimen.
If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced. Adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions.

2.3 Discontinuation of KADIAN
When a patient no longer requires therapy with KADIAN, use a gradual downward titration, of the dose every two to four days, to prevent signs and symptoms of withdrawal in the physically-dependent patient. Do not abruptly discontinue KADIAN.

2.4 Administration of KADIAN
Instruct patients to swallow KADIAN capsules intact. The pellets in the capsules are not to be crushed, dissolved, or chewed due to the risk of rapid release and absorption of a potentially fatal dose of morphine [see Warnings and Precautions (5.2)].
Alternatively, the contents of the KADIAN capsules (pellets) may be sprinkled over applesauce and then swallowed. This method is appropriate only for patients able to reliably swallow the applesauce without chewing. Other foods have not been tested and should not be substituted for applesauce. Instruct the patient to:
- Sprinkle the pellets onto a small amount of applesauce and consume immediately without chewing.
- Rinse the mouth to ensure all pellets have been swallowed.
- Discard any unused portion of the KADIAN capsules after the contents have been sprinkled on applesauce.
  The contents of the KADIAN capsules (pellets) may be administered through a 16 French gastrostomy tube.
- Flush the gastrostomy tube with water to ensure that it is wet.
- Sprinkle the KADIAN Pellets into 10 mL of water.
- Use a swirling motion to pour the pellets and water into the gastrostomy tube through a funnel.
- Rinse the beaker with a further 10 mL of water and pour this into the funnel.
- Repeat rinsing until no pellets remain in the beaker.
  Do not administer KADIAN pellets through a nasogastric tube.

3 DOSAGE FORMS & STRENGTHS
KADIAN contains white to off-white or tan colored polymer coated pellets, have an outer opaque capsule with colors as identified below and are available in twelve dose strengths:
Each 10 mg capsule has a light blue opaque cap printed with "KADIAN" and a light blue opaque body printed with "10 mg".
Each 20 mg capsule has a yellow opaque cap printed with "KADIAN" and a yellow opaque body printed with "20 mg".
Each 30 mg capsule has a blue violet opaque cap printed with "KADIAN" and a blue violet opaque body printed with "30 mg".
Each 40 mg capsule has a yellow opaque cap printed with "KADIAN" and a blue violet opaque body printed with "40 mg".
Each 50 mg capsule has a blue opaque cap printed with "KADIAN" and a blue opaque body printed with "50 mg".
Each 60 mg capsule has a pink opaque cap printed with "KADIAN" and a pink opaque body printed with "60 mg".
Each 70 mg capsule has a light blue opaque cap printed with "KADIAN" and a blue violet opaque body printed with "70 mg".
Each 80 mg capsule has a light orange opaque cap printed with "KADIAN" and a light orange opaque body printed with "80 mg".
Each 100 mg capsule has a green opaque cap printed with "KADIAN" and a green opaque body printed with "100 mg".
Each 130 mg capsule has a light orange opaque cap printed with "KADIAN" and a light brown opaque body printed with "130 mg".
Each 150 mg capsule has a green opaque cap printed with "KADIAN" and a light brown opaque body printed with "150 mg".
Each 200 mg capsule has a light brown opaque cap printed with "KADIAN" and light brown opaque body printed with "200 mg".

4 CONTRAINDICATIONS
KADIAN is contraindicated in patients with
- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected paralytic ileus
- Hypersensitivity (e.g., anaphylaxis) to morphine [see Adverse Reactions (6.2)]

5 WARNINGS AND PRECAUTIONS

5.1 Abuse Potential

KADIAN contains morphine, an opioid agonist and a Schedule II controlled substance. Morphine can be abused in a manner similar to other opioid agonists, legal or illicit. Opioid agonists are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing KADIAN in situations where there is concern about increased risks of misuse, abuse, or diversion. Concerns about abuse, addiction, and diversion should not, however, prevent the proper management of pain.

Assess each patient's risk for opioid abuse or addiction prior to prescribing KADIAN. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients at increased risk may still be appropriately treated with modified-release opioid formulations; however these patients will require intensive monitoring for signs of misuse, abuse, or addiction. Routinely monitor all patients receiving opioids for signs of misuse, abuse, and addiction because these drugs carry a risk for addiction even under appropriate medical use. Misuse or abuse of KADIAN by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of the opioid and pose a significant risk that could result in overdose and death [see Overdosage (10)].

Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product.

5.2 Life Threatening Respiratory Depression

Respiratory depression is the primary risk of KADIAN. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Respiratory depression from opioids is manifested by a reduced urge to breathe and a decreased rate of respiration, often associated with a "sighing" pattern of breathing (deep breaths separated by abnormally long pauses). Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status [see Overdosage (10)].

While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of KADIAN, the risk is greatest during the initiation of therapy or following a dose increase. Closely monitor patients for respiratory depression when initiating therapy with KADIAN and following dose increases. Instruct patients against use by individuals other than the patient for whom KADIAN was prescribed and to keep KADIAN out of the reach of children, as such inappropriate use may result in fatal respiratory depression.

To reduce the risk of respiratory depression, proper dosing and titration of KADIAN are essential [see Dosage and Administration (2.1, 2.2)]. Overestimating the KADIAN dose when converting patients from another opioid product can result in fatal overdose with the first dose. Respiratory depression has also been reported with use of modified-release opioids when used as recommended and not misused or abused.

To further reduce the risk of respiratory depression, consider the following:

- Proper dosing and titration are essential and KADIAN should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. KADIAN 100 mg, 130 mg, 150 mg, and 200 mg capsules are for use in opioid-tolerant patients only. Ingestion of this strength of KADIAN capsules or of the pellets within the capsule may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids.

- Instruct patients to swallow KADIAN capsules intact or to sprinkle the capsule contents on applesauce and swallow without chewing. The pellets in the capsules are not to be crushed, dissolved, or chewed. The resulting morphine dose may be fatal, particularly in opioid-naïve individuals.

- KADIAN is contraindicated in patients with respiratory depression and in patients with conditions that increase the risk of life-threatening respiratory depression [see Contraindications (4)].

5.3 Accidental Exposure

Accidental consumption of KADIAN, especially in children, can result in a fatal overdose of morphine.

5.4 Elderly, Cachectic, and Debilitated Patients

Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics due to poor fat stores, muscle wasting, or altered clearance compared to younger, healthier patients. Therefore, monitor such patients closely, particularly when initiating and titrating KADIAN and when KADIAN is given concomitantly with other drugs that depress respiration [see Warnings and Precautions (5.2)].

5.5 Use in Patients with Chronic Pulmonary Disease

Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression for respiratory depression, particularly when initiating therapy and titrating with KADIAN, as in these patients, even usual therapeutic doses of KADIAN may decrease

respiratory drive to the point of apnea [see Warnings and Precautions (5.2)]. Consider the use of alternative non-opioid analgesics in these patients if possible.

5.6 Interactions with CNS Depressants and Illicit Drugs
Hypotension, profound sedation, coma, or respiratory depression may result if KADIAN is used concomitantly with other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). When considering the use of KADIAN in a patient taking a CNS depressant, assess the duration of use of the CNS depressant and the patient's response, including the degree of tolerance that has developed to CNS depression. Additionally, consider the patient's use, if any, of alcohol or illicit drugs that cause CNS depression. If KADIAN therapy is to be initiated in a patient taking a CNS depressant, start with a lower KADIAN dose than usual and monitor patients for signs of sedation and respiratory depression and consider using a lower dose of the concomitant CNS depressant [see Drug Interactions (7.2)].

5.7 Hypotensive Effect
KADIAN may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g. phenothiazines or general anesthetics) [see Drug Interactions (7.2)]. Monitor these patients for signs of hypotension after initiating or titrating the dose of KADIAN. In patients with circulatory shock, KADIAN may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of KADIAN in patients with circulatory shock.

5.8 Use in Patients with Head Injury or Increased Intracranial Pressure
Monitor patients taking KADIAN who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors) for signs of sedation and respiratory depression, particularly when initiating therapy with KADIAN. KADIAN may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Opioids may also obscure the clinical course in a patient with a head injury.
Avoid the use of KADIAN in patients with impaired consciousness or coma.

5.9 Use in Patients with Gastrointestinal Conditions
KADIAN is contraindicated in patients with paralytic ileus. Avoid the use of KADIAN in patients with other GI obstruction.
The morphine in KADIAN may cause spasm of the sphincter of Oddi. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms. Opioids may cause increases in the serum amylase.

5.10 Use in Patients with Convulsive or Seizure Disorders
The morphine in KADIAN may aggravate convulsions in patients with convulsive disorders, and may induce or aggravate seizures in some clinical settings. Monitor patients with a history of seizure disorders for worsened seizure control during KADIAN therapy.

5.11 Avoidance of Withdrawal
Avoid the use of mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) in patients who have received or are receiving a course of therapy with a full opioid agonist analgesic, including KADIAN. In these patients, mixed agonists/ antagonists analgesics may reduce the analgesic effect and/or may precipitate withdrawal symptoms.
When discontinuing KADIAN, gradually taper the dose [see Dosage and Administration (2.3)]. Do not abruptly discontinue KADIAN.

5.12 Driving and Operating Machinery
KADIAN may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of KADIAN and know how they will react to the medication.

6 ADVERSE REACTIONS
The following serious adverse reactions are discussed elsewhere in the labeling:
- Respiratory Depression [see Warnings and Precautions (5.2)]
- Chronic Pulmonary Disease [see Warnings and Precautions (5.5)]
- Head Injuries and Increased Intracranial Pressure [see Warnings and Precautions (5.8)]
- Interactions with Other CNS Depressants [see Warnings and Precautions (5.6)]
- Hypotensive Effect [see Warnings and Precautions (5.7)]
- Gastrointestinal Effects[see Warnings and Precautions (5.9)]

• Seizures [see Warnings and Precautions (5.10)]

In the randomized study, the most common adverse reactions with KADIAN therapy were drowsiness, constipation, nausea, dizziness, and anxiety. The most common adverse reactions leading to study discontinuation were nausea, constipation (may be severe), vomiting, fatigue, dizziness, pruritus, and somnolence.

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Clinical trial patients with chronic cancer pain (n=227)

(AE by Body System as seen in 2% or more of patients)	Percentage %
CENTRAL NERVOUS SYSTEM	**28**
Drowsiness	9
Dizziness	6
Anxiety	5
Confusion	4
Dry Mouth	3
Tremor	2
GASTROINTESTINAL	**26**
Constipation	9
Nausea	7
Diarrhea	3
Anorexia	3
Abdominal pain	3
Vomiting	2
BODY AS A WHOLE	**16**
Pain	3
Disease progression	3
Chest pain	2
Diaphoresis	2
Fever	2
Asthenia	2
Accidental Injury	2
RESPIRATORY	**3**
Dyspnea	3
SKIN & APPENDAGES	**3**
Rash	3
METABOLIC & NUTRITIONAL	**3**
Peripheral edema	3
HEMIC & LYMPHATIC	**4**
Anemia	2
Leukopenia	2

In clinical trials in patients with chronic cancer pain, the most common adverse events reported by patients at least once during therapy were drowsiness (9%), constipation (9%), nausea (7%), dizziness (6%), and anxiety (6%). Other less common side effects expected from KADIAN or seen in less than 2% of patients in the clinical trials were:

• Body as a Whole: Headache, chills, flu syndrome, back pain, malaise, withdrawal syndrome

• Cardiovascular: Tachycardia, atrial fibrillation, hypotension, hypertension, pallor, facial flushing, palpitations, bradycardia, syncope

• Central Nervous System: Confusion, anxiety, abnormal thinking, abnormal dreams, lethargy, depression, loss of concentration, insomnia, amnesia, paresthesia, agitation, vertigo, foot drop, ataxia, hypesthesia, slurred speech, hallucinations, vasodilation, euphoria, apathy, seizures, myoclonus

• Endocrine:Hyponatremia due to inappropriate ADH secretion, gynecomastia

- Gastrointestinal: Dysphagia, dyspepsia, stomach atony disorder, gastro-esophageal reflux, delayed gastric emptying, biliary colic
- Hemic and Lymphatic: Thrombocytopenia
- Metabolic and Nutritional:Hyponatremia, edema
- Musculoskeletal:Back pain, bone pain, arthralgia
- Respiratory:Hiccup, rhinitis, atelectasis, asthma, hypoxia, respiratory insufficiency, voice alteration, depressed cough reflex, non-cardiogenic pulmonary edema
- Skin and Appendages:Decubitus ulcer, pruritus, skin flush
- Special Senses:Amblyopia, conjunctivitis, miosis, blurred vision, nystagmus, diplopia
- Urogenital:Urinary abnormality, amenorrhea, urinary retention, urinary hesitancy, reduced libido, reduced potency, prolonged labor

Four-Week Open-Label Safety Study
In the open-label, 4-week safety study, 1418 patients' ages 18 to 85 with chronic, non-malignant pain (e.g., back pain, osteoarthritis, neuropathic pain) were enrolled. The most common adverse events reported at least once during therapy were constipation (12%), nausea (9%), and somnolence (3%). Other less common side effects occurring in less than 3% of patients were vomiting, pruritus, dizziness, sedation, dry mouth, headache, fatigue, and rash.

6.2 Post-marketing Experience
Anaphylaxis has been reported with ingredients contained in KADIAN. Advise patients how to recognize such a reaction and when to seek medical attention.

7 DRUG INTERACTIONS

7.1 Alcohol
Concomitant use of alcohol with KADIAN can result in an increase of morphine plasma levels and potentially fatal overdose of morphine. [see Clinical Pharmacology (12.3)].

7.2 CNS Depressants
Concurrent use of KADIAN and other central nervous system (CNS) depressants (e.g. sedatives, hypnotics, general anesthetics, antiemetics, phenothiazines, other tranquilizers, and alcohol) can increase the risk of respiratory depression, hypotension, and profound sedation or coma. Monitor patients receiving CNS depressants and KADIAN for signs of respiratory depression and hypotension. When such combined therapy is contemplated, reduce the initial dose of one or both agents.

7.3 Mixed Agonist/Antagonist Opioid Analgesics
Mixed agonist/antagonist analgesics may reduce the analgesic effect of KADIAN and/or may precipitate withdrawal symptoms in these patients. Avoid the use of agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, butorphanol) in patients receiving KADIAN.

7.4 Muscle Relaxants
Opioids may enhance the neuromuscular blocking action of skeletal relaxants and produce an increased degree of respiratory depression. Monitor patients receiving muscle relaxants and KADIAN for signs of respiratory depression that may be greater than otherwise expected.

7.5 Monoamine Oxidase Inhibitors (MAOIs)
The effects of morphine may be potentiated by MAOIs. Monitor patients on concurrent therapy with an MAOI and KADIAN for increased respiratory and central nervous system depression. KADIAN should not be used in patients taking MAOIs or within 14 days of stopping such treatment.

7.6 Cimetidine
Cimetidine can potentiate morphine-induced respiratory depression. There is a report of confusion and severe respiratory depression when a patient undergoing hemodialysis was concurrently administered morphine and cimetidine. Monitor patients for respiratory depression when KADIAN and cimetidine are used concurrently.

7.7 Diuretics
Morphine can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone. Morphine may also lead to acute retention of urine by causing spasm of the sphincter of the bladder, particularly in men with enlarged prostates.

7.8 Anticholinergics
Anticholinergics or other drugs with anticholinergic activity when used concurrently with opioid analgesics may result in increased risk of urinary retention and/or severe constipation, which may lead to paralytic ileus. Monitor patients for signs of urinary retention or reduced gastric motility when KADIAN is used concurrently with anticholinergic drugs.

7.9 P-Glycoprotein (PGP) Inhibitors
PGP inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine by about two-fold. Monitor patients for signs of respiratory and central nervous system depression when PGP inhibitors are used concurrently with KADIAN.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Teratogenic Effects (Pregnancy Category C)
No formal studies to assess the teratogenic effects of morphine in animals have been conducted. It is also not known whether morphine can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Morphine should be given to a pregnant woman only if clearly needed.
In humans, the frequency of congenital anomalies has been reported to be no greater than expected among the children of 70 women who were treated with morphine during the first four months of pregnancy or in 448 women treated with morphine anytime during pregnancy. Furthermore, no malformations were observed in the infant of a woman who attempted suicide by taking an overdose of morphine and other medication during the first trimester of pregnancy.
Several literature reports indicate that morphine administered subcutaneously during the early gestational period in mice and hamsters produced neurological, soft tissue and skeletal abnormalities. With one exception, the effects that have been reported were following doses that were maternally toxic and the abnormalities noted were characteristic of those observed when maternal toxicity is present.
In one study, following subcutaneous infusion of doses greater than or equal to 0.15 mg/kg to mice, exencephaly, hydronephrosis, intestinal hemorrhage, split supraoccipital, malformed sternebrae, and malformed xiphoid were noted in the absence of maternal toxicity. In the hamster, morphine sulfate given subcutaneously on gestation day 8 produced exencephaly and cranioschisis. In rats treated with subcutaneous infusions of morphine during the period of organogenesis, no teratogenicity was observed. No maternal toxicity was observed in this study; however, increased mortality and growth retardation were seen in the offspring. In two studies performed in the rabbit, no evidence of teratogenicity was reported at subcutaneous doses up to 100 mg/kg.
Nonteratogenic Effects
Infants born to mothers who have taken opioids chronically may exhibit neonatal withdrawal syndrome [see Use in Specific Populations (8.6)], reversible reduction in brain volume, small size, decreased ventilatory response to CO_2 and increased risk of sudden infant death syndrome. Morphine sulfate should be used by a pregnant woman only if the need for opioid analgesia clearly outweighs the potential risks to the fetus.
Controlled studies of chronic *in utero* morphine exposure in pregnant women have not been conducted. Published literature has reported that exposure to morphine during pregnancy in animals is associated with reduction in growth and a host of behavioral abnormalities in the offspring. Morphine treatment during gestational periods of organogenesis in rats, hamsters, guinea pigs and rabbits resulted in the following treatment-related embryotoxicity and neonatal toxicity in one or more studies: decreased litter size, embryo-fetal viability, fetal and neonatal body weights, absolute brain and cerebellar weights, delayed motor and sexual maturation, and increased neonatal mortality, cyanosis and hypothermia. Decreased fertility in female offspring, and decreased plasma and testicular levels of luteinizing hormone and testosterone, decreased testes weights, seminiferous tubule shrinkage, germinal cell aplasia, and decreased spermatogenesis in male offspring were also observed. Decreased litter size and viability were observed in the offspring of male rats administered morphine (25 mg/kg, IP) for 1 day prior to mating. Behavioral abnormalities resulting from chronic morphine exposure of fetal animals included altered reflex and motor skill development, mild withdrawal, and altered responsiveness to morphine persisting into adulthood.

8.2 Labor and Delivery
KADIAN is not recommended for use in women during and immediately prior to labor, where shorter acting analgesics or other analgesic techniques are more appropriate. Occasionally, opioid analgesics may prolong labor through actions which temporarily reduce the strength, duration and frequency of uterine contractions. However, this effect is not consistent and may be offset by an increased rate of cervical dilatation which tends to shorten labor.
Opioids cross the placenta and may produce respiratory depression and psychophysiologic effects in neonates. Closely observe neonates whose mothers received opioid analgesics during labor for signs of respiratory depression. Have a specific opioid antagonist, such as naloxone or nalmefene, available for reversal of opioid-induced respiratory depression in the neonate.

8.3 Nursing Mothers
Morphine is excreted in breast milk, with a milk to plasma morphine AUC ratio of approximately 2.5:1. The amount of morphine received by the infant varies depending on the maternal plasma concentration, the amount of milk ingested by the infant, and the extent of first pass metabolism.
Withdrawal symptoms can occur in breast-feeding infants when maternal administration of morphine is stopped.

Because of the potential for adverse reactions in nursing infants from KADIAN, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use
The safety and efficacy of KADIAN in patients less than 18 years have not been established.

8.5 Geriatric Use
Clinical studies of KADIAN did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

8.6 Neonatal Opioid Withdrawal Syndrome
Chronic maternal use of morphine during pregnancy can affect the fetus with subsequent withdrawal signs. Neonatal withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration and severity of neonatal withdrawal syndrome vary based on the drug used, duration of use, the dose of last maternal use, and rate of elimination drug by the newborn. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening and should be treated according to protocols developed by neonatology experts.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance
KADIAN contains morphine, a Schedule II controlled substance with a high potential for abuse similar to other opioids including fentanyl, hydromorphone, methadone, oxycodone, and oxymorphone. KADIAN can be abused and is subject to misuse, addiction, and criminal diversion [see Warnings and Precautions (5.1)].
The high drug content in extended-release formulations adds to the risk of adverse outcomes from abuse and misuse.

9.2 Abuse
All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.
Drug abuse is the intentional non-therapeutic use of an over-the-counter or prescription drug, even once, for its rewarding psychological or physiological effects. Drug abuse includes, but is not limited to, the following examples: the use of a prescription or over-the counter drug to get "high", or the use of steroids for performance enhancement and muscle build up.
Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal.
"Drug seeking" behavior is very common to addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated claims of loss of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). "Doctor shopping" (visiting multiple prescribers) to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.
Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction.
KADIAN, like other opioids, can be diverted for non-medical use into illicit channels of distribution. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests as required by state law, is strongly advised.
Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to reduce abuse of opioid drugs.
Risks Specific to Abuse of KADIAN
KADIAN is for oral use only. Abuse of KADIAN poses a risk of overdose and death. This risk is increased with concurrent abuse of KADIAN with alcohol and other substances. Taking cut, broken, chewed, crushed, or dissolved KADIAN enhances drug release and increases the risk of over dose and death.
Due to the presence of talc as one of the excipients in KADIAN, parenteral abuse can be expected to result in local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

9.3 Dependence
Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects.
Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity, e.g., naloxone, nalmefene, or mixed agonist/antagonist analgesics (pentazocine, butorphanol, buprenorphine, nalbuphine). Physical dependence may not occur to a

clinically significant degree until after several days to weeks of continued opioid usage KADIAN should not be abruptly discontinued [see Dosage and Administration (2.3)]. If KADIAN is abruptly discontinued in a physically-dependent patient, an abstinence syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate.

Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal symptoms [see Use in Specific Populations (8.2, 8.6)].

10 OVERDOSAGE

Clinical Presentation

Acute overdosage with morphine is manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, sometimes, pulmonary edema, bradycardia, hypotension, and death. Marked mydriasis rather than miosis may be seen due to severe hypoxia in overdose situations.

Treatment of Overdose

In cases of overdose, priorities are the re-establishment of a patent airway and institution of assisted or controlled ventilation if needed. Employ other supportive measures (including oxygen and vasopressors) in the management of cardiac and/or pulmonary failure as needed. Cardiac arrest or arrhythmias will require advanced life support techniques.

The opioid antagonists, naloxone or nalmefene, are specific antidotes to respiratory depression resulting from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to morphine overdose. Such agents should be administered cautiously to patients who are known, or suspected to be, physically dependent on KADIAN. In such cases, an abrupt or complete reversal of opioid effects may precipitate an acute withdrawal syndrome. Because the duration of reversal would be expected to be less than the duration of action of morphine in KADIAN, carefully monitor the patient until spontaneous respiration is reliably re-established. KADIAN will continue to release morphine adding to the morphine load for up to 24 hours after administration, necessitating prolonged monitoring. If the response to opioid antagonists is suboptimal or not sustained, additional antagonist should be given as directed in the product's prescribing information.

In an individual physically dependent on opioids, administration of the usual dose of the antagonist will precipitate an acute withdrawal. The severity of the withdrawal produced will depend on the degree of physical dependence and the dose of the antagonist administered. If a decision is made to treat serious respiratory depression in the physically dependent patient, administration of the antagonist should be begun with care and by titration with smaller than usual doses of the antagonist.

11 DESCRIPTION

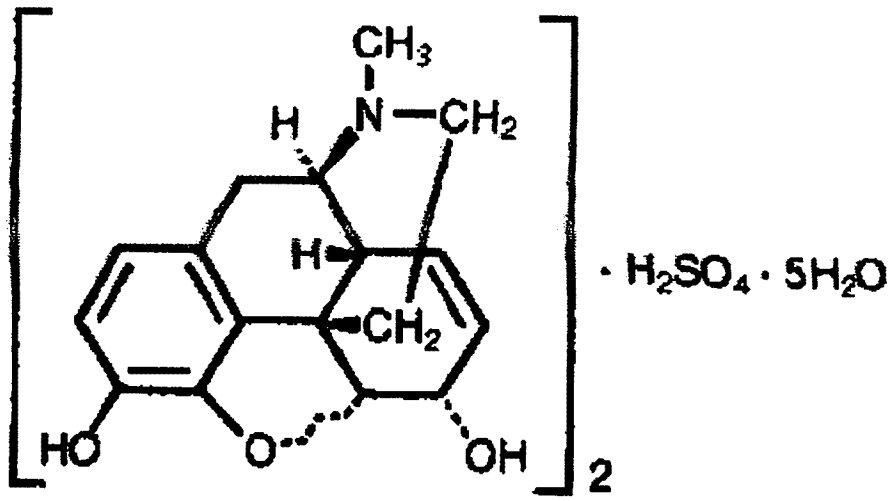
KADIAN (morphine sulfate) Extended-Release capsules are for oral use and contain pellets of morphine sulfate. Morphine sulfate is an agonist at the mu-opioid receptor.

Each KADIAN extended-release capsule contains either 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, or 200 mg of Morphine Sulfate USP and the following inactive ingredients common to all strengths: hypromellose, ethylcellulose, methacrylic acid copolymer, polyethylene glycol, diethyl phthalate, talc, corn starch, and sucrose.

The capsule shells contain gelatin, silicon dioxide, sodium lauryl sulfate, titanium dioxide, and black ink, D&C red #28, FD&C blue #1 (10 mg), D&C yellow #10 (20 mg), FD&C red #3, FD&C blue #1 (30 mg), D&C yellow #10, FD&C blue #1, FD&C red #3 (40 mg), D&C red #28, FD&C red #40, FD&C blue #1 (50 mg), D&C red #28, FD&C red #40, FD&C blue #1 (60 mg), D&C red #28, FD&C blue #1, FD&C red #3 (70 mg), FD&C blue #1, FD&C red #40, FD&C yellow #6 (80 mg), D&C yellow #10, FD&C blue #1 (100 mg), FD&C red #40, FD&C blue #1, FD&C yellow #6, black iron oxide, red iron oxide, yellow iron oxide (130 mg), FD&C blue #1, D&C yellow #10, black iron oxide, red iron oxide, yellow iron oxide (150 mg), black iron oxide, yellow iron oxide, red iron oxide (200 mg). The imprint ink contains black iron oxide, potassium hydroxide, propylene glycol, and shellac.

The chemical name of morphine sulfate is 7,8-didehydro-4,5 (- epoxy-17-methyl-morphinan-3,6 (- diol sulfate (2:1) (salt) pentahydrate. The empirical formula is $(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$ and its molecular weight is 758.85.

Morphine sulfate is an odorless, white, crystalline powder with a bitter taste. It has a solubility of 1 in 21 parts of water and 1 in 1000 parts of alcohol, but is practically insoluble in chloroform or ether. The octanol: water partition coefficient of morphine is 1.42 at physiologic pH and the pK_b is 7.9 for the tertiary nitrogen (mostly ionized at pH 7.4). Its structural formula is:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Morphine sulfate, an opioid agonist, is relatively selective for the mu receptor, although it can interact with other opioid receptors at higher doses. In addition to analgesia, the widely diverse effects of morphine sulfate include analgesia, dysphoria, euphoria, somnolence, respiratory depression, diminished gastrointestinal motility, altered circulatory dynamics, histamine release, physical dependence, and alterations of the endocrine and autonomic nervous systems.

Morphine produces both its therapeutic and its adverse effects by interaction with one or more classes of specific opioid receptors located throughout the body. Morphine acts as a full agonist, binding with and activating opioid receptors at sites in the peri-aqueductal and peri-ventricular grey matter, the ventro-medial medulla and the spinal cord to produce analgesia.

Effects on the Central Nervous System

The principal actions of therapeutic value of morphine are analgesia and sedation. Specific CNS opiate receptors and endogenous compounds with morphine-like activity have been identified throughout the brain and spinal cord and are likely to play a role in the expression of analgesic effects. Morphine produces respiratory depression by direct action on brainstem respiratory centers. The mechanism of respiratory depression involves a reduction in the responsiveness of the brainstem respiratory centers to increases in carbon dioxide tension, and to electrical stimulation. Morphine depresses the cough reflex by direct effect on the cough center in the medulla. Morphine causes miosis, even in total darkness, and little tolerance develops to this effect. Pinpoint pupils are a sign of opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origins may produce similar findings). Marked mydriasis rather than miosis may be seen with worsening hypoxia in the setting of morphine overdose.

Effects on the Gastrointestinal Tract and Other Smooth Muscle

Gastric, biliary and pancreatic secretions are decreased by morphine. Morphine causes a reduction in motility associated with an increase in tone in the antrum of the stomach and duodenum. Digestion of food in the small intestine is delayed and propulsive contractions are decreased. Propulsive peristaltic waves in the colon are decreased, while tone is increased to the point of spasm. The end result is constipation. Morphine can cause a marked increase in biliary tract pressure as a result of spasm of the sphincter of Oddi.

Effects on the Cardiovascular System

Morphine produces peripheral vasodilation which may result in orthostatic hypotension or syncope. Release of histamine may be induced by morphine and can contribute to opioid-induced hypotension. Manifestations of histamine release or peripheral vasodilation may include pruritus, flushing, red eyes and sweating.

Effects on the Endocrine System

Opioids inhibit the secretion of ACTH, cortisol, and luteinizing hormone (LH) in humans. They also stimulate prolactin, growth hormone (GH) secretion, and pancreatic secretion of insulin and glucagon.

Effects on the Immune System

Opioids have been shown to have a variety of effects on components of the immune system in *in vitro* and animal models. The clinical significance of these findings is unknown. Overall, the effects of opioids appear to be modestly immunosuppressive.

12.2 Pharmacodynamics

Plasma Level-Analgesia Relationships

While plasma morphine-efficacy relationships can be demonstrated in non-tolerant individuals, they are influenced by a wide variety of factors and are not generally useful as a guide to the clinical use of morphine. The effective dose in opioid-tolerant patients may be 10 to 50 times as great (or greater) than the appropriate dose for opioid-naïve individuals. Dosages of morphine should be chosen and must be titrated on the basis of clinical evaluation of the patient and the balance between therapeutic and adverse effects.

CNS Depressant/Alcohol Interaction

Additive pharmacodynamic effects may be expected when KADIAN is used in conjunction with alcohol, other opioids, or illicit drugs that cause central nervous system depression.

12.3 Pharmacokinetics

Absorption

KADIAN capsules contain polymer coated extended-release pellets of morphine sulfate that release morphine significantly more slowly than oral morphine solution. Following the administration of oral morphine solution, approximately 50% of the morphine absorbed reaches the systemic circulation within 30 minutes compared to 8 hours with an equal amount of KADIAN. Because of pre-systemic elimination, only about 20 to 40% of the administered dose reaches the systemic circulation.

Both dose-normalized C_{max} and dose-normalized AUC_{0-48hr} values of morphine after a single dose administration of KADIAN in healthy volunteers are less than those for morphine oral solution or an extended-release tablet formulation (Table 1).

When KADIAN was given twice daily to 24 patients with chronic pain due to malignancy, steady state was achieved in about two days. At steady state, KADIAN has a significantly lower C_{max} and a higher C_{min} than equivalent doses of oral morphine solution given every 4 hrs and an extended-release tablet given twice daily. When given once daily to 24 patients with malignancy, KADIAN had a similar C_{max} and higher C_{min} at steady state when compared to an extended-release morphine tablets, given twice daily at an equivalent total daily dosage (see Table 1).

The single-dose pharmacokinetics of KADIAN are linear over the dosage range of 30 to 100 mg.

Table 1: Mean pharmacokinetic parameters (% coefficient variation) resulting from a fasting single dose study in normal volunteers and a multiple-dose study in patients with cancer pain.

Regimen/Dosage Form	AUC#,+ (ng.h/mL)	C_{max}+ (ng/mL)	T_{max} (h)	C_{min}+ (ng/mL)	Fluctuation*
Single Dose (n=24)					
KADIAN Capsule	271.0	15.6	8.6	na^	na
	(19.4)	(24.4)	(41.1)		
Extended-Release Tablet	304.3	30.5	2.5	na	na
	(19.1)	(32.1)	(52.6)		
Morphine Solution	362.4	64.4	0.9	na	na
	(42.6)	(38.2)	(55.8)		
Multiple Dose (n=24)					
KADIAN Capsule Once Daily	500.9	37.3	10.3	9.9	3.0
	(38.6)	(37.7)	(32.2)	(52.3)	(45.5)
Extended-Release Tablet Twice Daily	457.3	36.9	4.4	7.6	4.1
	(40.2)	(42.0)	(53.0)	(60.3)	(51.5)

For single dose AUC = AUC_{0-48h}, for multiple dose AUC = AUC_{0-24h} at steady state

+ For single dose parameter normalized to 100 mg, for multiple dose parameter normalized to 100 mg per 24 hours

* Steady-state fluctuation in plasma concentrations = C_{max}-C_{min}/C_{min}

^ Not applicable

Food effect: While concurrent administration of food slows the rate of absorption of KADIAN, the extent of absorption is not affected and KADIAN can be administered without regard to meals.

Distribution

Once absorbed, morphine is distributed to skeletal muscle, kidneys, liver, intestinal tract, lungs, spleen and brain. The volume of distribution of morphine is approximately 3 to 4 L/kg. Morphine is 30 to 35% reversibly bound to plasma proteins. Although the primary site of action of morphine is in the CNS, only small quantities pass the blood-brain barrier. Morphine also crosses the placental membranes [see Use in Special Populations (8.1)] and has been found in breast milk [see Use in Specific Populations (8.3)].

Metabolism

Major pathways of morphine metabolism include glucuronidation in the liver to produce metabolites including morphine-3-glucuronide, M3G (about 50%) and morphine-6-glucuronide, M6G (about 5 to 15%) and sulfation in the liver to produce morphine-3-etheral sulfate. A small fraction (less than 5%) of morphine is demethylated. M3G has no significant contribution to the analgesic

activity. Although M6G does not readily cross the blood-brain barrier, it has been shown to have opioid agonist and analgesic activity in humans.

Studies in healthy subjects and cancer patients have shown that the glucuronide metabolite to morphine mean molar ratios (based on AUC) are similar after both single doses and at steady state for KADIAN, 12-hour extended-release morphine sulfate tablets and morphine sulfate solution.

Excretion

Approximately 10% of a morphine dose is excreted unchanged in the urine. Most of the dose is excreted in the urine as M3G and M6G which are then renally excreted. A small amount of the glucuronide metabolites is excreted in the bile and there is some minor enterohepatic cycling. Seven to 10% of administered morphine is excreted in the feces.

The mean adult plasma clearance of morphine is about 20 to 30 mL/minute/kg. The effective terminal half-life of morphine after IV administration is reported to be approximately 2 hours. The terminal elimination half-life of morphine following a single dose of KADIAN administration is approximately 11 to 13 hours.

Special Populations

Geriatric Patients: The pharmacokinetics of KADIAN have not been investigated in elderly patients (>65 years) although such patients were included in the clinical studies.

Pediatric Patients: The pharmacokinetics of KADIAN have not been evaluated in a pediatric population.

Gender: No meaningful differences between male and female patients were demonstrated in the analysis of the pharmacokinetic data from clinical studies.

Race: Chinese subjects given intravenous morphine in one study had a higher clearance when compared to Caucasian subjects (1852 ± 116 mL/min versus 1495 ± 80 mL/min).

Hepatic Impairment: The pharmacokinetics of morphine were found to be significantly altered in individuals with alcoholic cirrhosis. The clearance was found to decrease with a corresponding increase in half-life. The M3G and M6G to morphine plasma AUC ratios also decreased in these patients indicating a decrease in metabolic activity. Adequate studies of the pharmacokinetics of morphine in patients with severe hepatic impairment have not been conducted.

Renal Impairment: The pharmacokinetics of morphine are altered in patients with renal failure. The AUC is increased and clearance is decreased. Metabolites, M3G and M6G accumulate several fold in patients with renal failure compared to healthy subjects. Adequate studies of the pharmacokinetics of morphine in patients with severe renal impairment have not been conducted.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Studies in animals to evaluate the carcinogenic potential of morphine have not been conducted.

Mutagenesis: No formal studies to assess the mutagenic potential of morphine have been conducted. In the published literature, morphine was found to be mutagenic *in vitro* increasing DNA fragmentation in human T-cells. Morphine was reported to be mutagenic in the *in vivo* mouse micronucleus assay and positive for the induction of chromosomal aberrations in mouse spermatids and murine lymphocytes. Mechanistic studies suggest that the *in vivo* clastogenic effects reported with morphine in mice may be related to increases in glucocorticoid levels produced by morphine in this species. In contrast to the above positive findings, *in vitro* studies in the literature have also shown that morphine did not induce chromosomal aberrations in human leukocytes or translocations or lethal mutations in *Drosophila*.

Impairment of Fertility: No formal nonclinical studies to assess the potential of morphine to impair fertility have been conducted. Several nonclinical studies from the literature have demonstrated adverse effects on male fertility in the rat from exposure to morphine. One study in which male rats were administered morphine sulfate subcutaneously prior to mating (up to 30 mg/kg twice daily) and during mating (20 mg/kg twice daily) with untreated females, a number of adverse reproductive effects including reduction in total pregnancies, higher incidence of pseudopregnancies, and reduction in implantation sites were seen. Studies from the literature have also reported changes in hormonal levels (i.e. testosterone, luteinizing hormone, serum corticosterone) following treatment with morphine. These changes may be associated with the reported effects on fertility in the rat.

16 HOW SUPPLIEDSTORAGE AND HANDLING

KADIAN capsules contain white to off-white or tan colored polymer coated extended-release pellets of morphine sulfate and are available in twelve dose strengths.

	KADIAN 10 mg	KADIAN 20 mg	KADIAN 30 mg	KADIAN 40 mg
Capsule Description	size 4, light blue opaque cap printed with "KADIAN" and light blue opaque body printed with "10 mg".	size 4, yellow opaque cap printed with "KADIAN" and yellow opaque body printed with "20 mg".	size 4, blue violet opaque cap printed with "KADIAN" and blue violet opaque body printed with "30 mg".	size 2, yellow opaque cap printed with "KADIAN" and blue violet opaque body printed with "40 mg".
Bottle Size	100	100	100	100
NDC #	NDC 46987-410-11	NDC 46987-322-11	NDC 46987-325-11	NDC 46987-327-11

	KADIAN 50 mg	KADIAN 60 mg	KADIAN 70 mg	KADIAN 80 mg
Capsule Description	size 2, blue opaque cap printed with "KADIAN" and blue opaque body printed with "50 mg".	size 1, pink opaque cap printed with "KADIAN" and pink opaque body printed with "60 mg".	size 1EL, light blue opaque cap printed with "KADIAN" and blue violet opaque body printed with "70 mg".	size 0, light orange opaque cap printed with "KADIAN" and light orange opaque body printed with "80 mg".
Bottle Size	100	100	100	100
NDC #	NDC 46987-323-11	NDC 46987-326-11	NDC 46987-328-11	NDC 46987-412-11

	KADIAN 100 mg	KADIAN 130 mg	KADIAN 150 mg	KADIAN 200 mg
Capsule Description	size 0, green opaque cap printed with "KADIAN" and green opaque body printed with "100 mg".	size 1, light orange opaque cap printed with "KADIAN" and light brown opaque body printed with "130 mg".	size 1EL, green opaque cap printed with "KADIAN" and light brown opaque body printed with "150 mg".	size 0, light brown opaque cap printed with "KADIAN" and light brown opaque body printed with "200 mg".
Bottle Size	100	100	100	100
NDC #	NDC 46987-324-11	NDC 46987-329-11	NDC 46987-330-11	NDC 46987-377-11

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from light and moisture. Dispense in a sealed tamper-evident, childproof, light-resistant container.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide)

Abuse Potential

Inform patients that KADIAN contains morphine, a Schedule II controlled substance that is subject to abuse. Instruct patients not to share KADIAN with others and to take steps to protect KADIAN from theft or misuse.

Life-threatening Respiratory Depression

Discuss the risk of respiratory depression with patients, explaining that the risk is greatest when starting KADIAN or when the dose is increased. Advise patients how to recognize respiratory depression and to seek medical attention if they are experiencing breathing difficulties.

Accidental Exposure

Instruct patients to take steps to store KADIAN securely. Accidental exposure, especially in children, may result in serious harm or death. Advise patients to dispose of unused KADIAN by flushing the capsules down the toilet.

Risks from Concomitant Use of Alcohol and other CNS Depressants

Inform patients that the concomitant use of alcohol with KADIAN can increase the risk of life-threatening respiratory depression. Inform patients that potentially serious additive effects may occur if KADIAN is used with other CNS depressants, and not to use such drugs unless supervised by a health care provider.

Important Administration Instructions

Instruct patients how to properly take KADIAN, including the following:

- Swallowing KADIAN capsules whole or sprinkling the capsule contents on applesauce and then swallowing without chewing
- Not crushing, chewing, or dissolving the pellets in the capsules
- Using KADIAN exactly as prescribed to reduce the risk of life-threatening adverse reactions (e.g., respiratory depression)
- Not discontinuing KADIAN without first discussing the need for a tapering regimen with the prescriber

Hypotension

Inform patients that KADIAN may cause orthostatic hypotension and syncope. Instruct patients how to recognize symptoms of low blood pressure and how to reduce the risk of serious consequences should hypotension occur (e.g., sit or lie down, carefully rise from a sitting or lying position).

Driving or Operating Heavy Machinery

Inform patients that KADIAN may impair the ability to perform potentially hazardous activities such as driving a car or operating heavy machinery. Advise patients not to perform such tasks until they know how they will react to the medication.

Constipation

Advise patients of the potential for severe constipation, including management instructions and when to seek medical attention.

Anaphylaxis
Inform patients that anaphylaxis has been reported with KADIAN. Advise patients how to recognize such a reaction and when to seek medical attention.
Pregnancy
Advise female patients that KADIAN can cause fetal harm and to inform the prescriber if they are pregnant or plan to become pregnant.
Distributed by: Actavis Kadian LLC, 60 Columbia Rd., Bldg. B, Morristown, NJ 07960 USA
KADIAN® is a registered trademark of Actavis Elizabeth LLC.
40-9166

MEDICATION GUIDE
KADIAN® (key-dee-uhn)
(morphine sulfate extended-release) Capsules, CII
KADIAN® is:
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about KADIAN®:

- Get emergency help right away if you take too much KADIAN® (overdose). KADIAN® overdose can cause life threatening breathing problems that can lead to death.

- Never give anyone else your KADIAN®. They could die from taking it. Store KADIAN® away from children and in a safe place to prevent stealing or abuse. Selling or giving away KADIAN® is against the law.

Do not take KADIAN® if you have:
- severe asthma, trouble breathing, or other lung problems.

- a bowel blockage or have narrowing of the stomach or intestines.

Before taking KADIAN®, tell your healthcare provider if you have a history of:
- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** KADIAN® may harm your unborn baby.

- **breastfeeding.** KADIAN® passes into breast milk and may harm your baby.

- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking KADIAN®:
- Do not change your dose. Take KADIAN® exactly as prescribed by your healthcare provider.

- Take your prescribed dose at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take KADIAN® as soon as possible and then take your next dose 12 or 24 hours later as directed by your healthcare provider. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.

- Swallow KADIAN® whole. Do not cut, break, chew, crush, dissolve, or inject KADIAN®.

- If you cannot swallow KADIAN® capsules, see the detailed Instructions for Use.

- **Call your healthcare provider if the dose you are taking does not control your pain.**

- **Do not stop taking KADIAN® without talking to your healthcare provider.**

- After you stop taking KADIAN®, flush any unused capsules down the toilet.

While taking KADIAN® Do Not:

- Drive or operate heavy machinery, until you know how KADIAN® affects you. KADIAN® can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of KADIAN® are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of KADIAN®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

KADIAN® is a registered trademark of Actavis Elizabeth LLC.
Distributed by: Actavis Kadian LLC, 60 Columbia Rd., Bldg. B, Morristown, NJ 07960 USA, www.KADIAN.com or call 1-888-496-3082
This Medication Guide has been approved by the U.S. Food and Drug Administration. Issue: July 2012

INSTRUCTIONS FOR USE

KADIAN® (key-dee-uhn)
(morphine sulfate extended-release) Capsules, CII

If you cannot swallow KADIAN® capsules, tell your healthcare provider. There may be another way to take KADIAN® that may be right for you. If your doctor tells you that you can take KADIAN® using this other way, follow these steps:
KADIAN® can be opened and the pellets inside the capsule can be sprinkled over apple sauce, as follows:

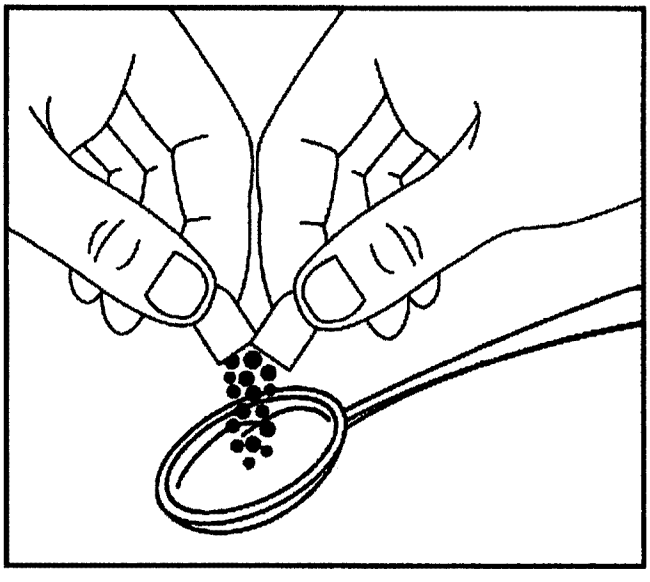


Figure 1

- Open the KADIAN® capsule and sprinkle the pellets over approximately one tablespoon of apple sauce (Figure 1).

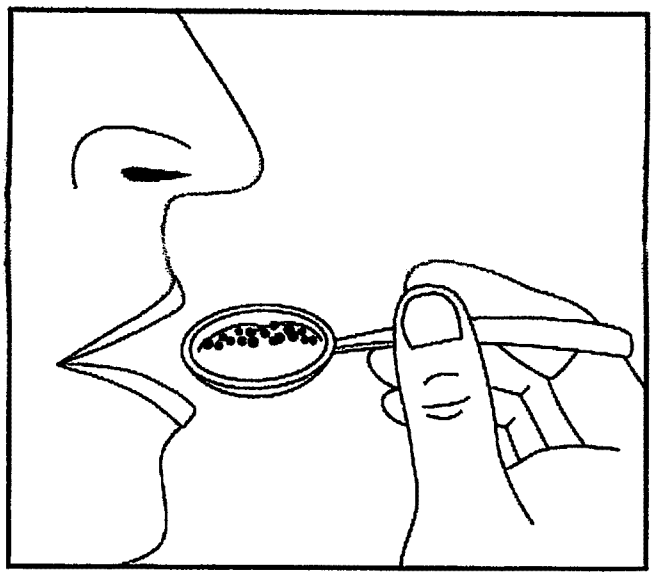


Figure 2

- Swallow all of the apple sauce and pellets right away. Do not save any of the apple sauce and pellets for another dose (Figure 2).

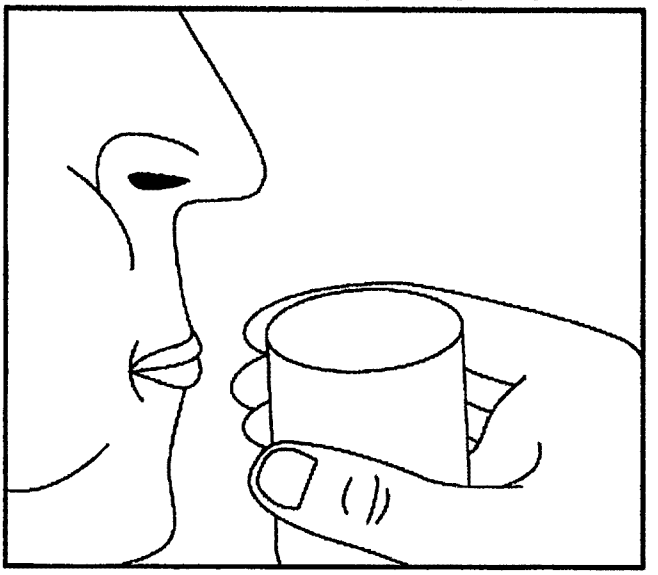


Figure 3

- Rinse your mouth to make sure you have swallowed all of the pellets. Do not chew the pellets (Figure 3).

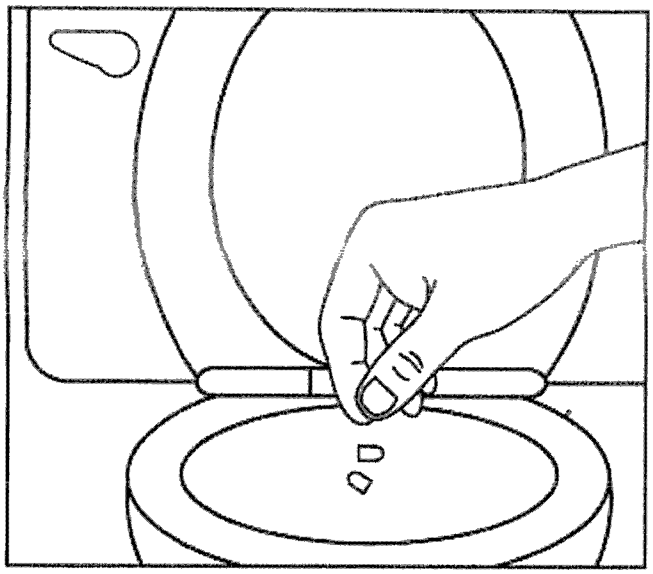
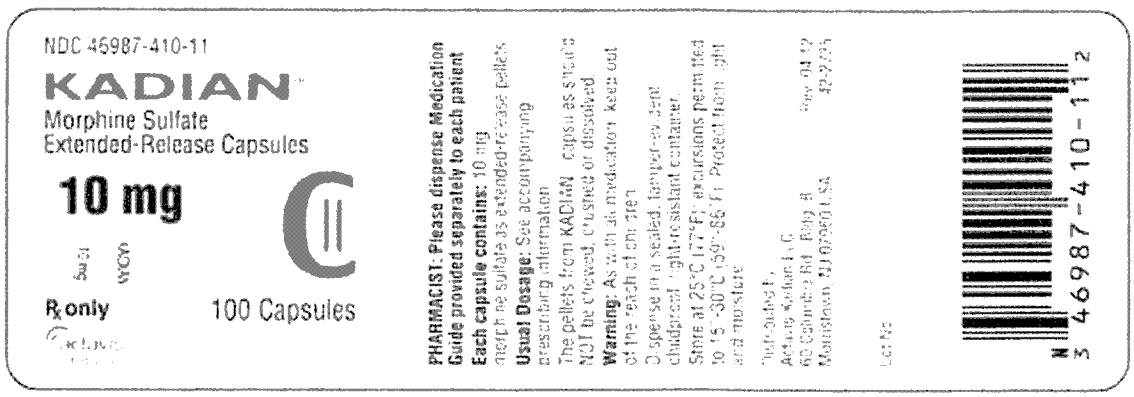


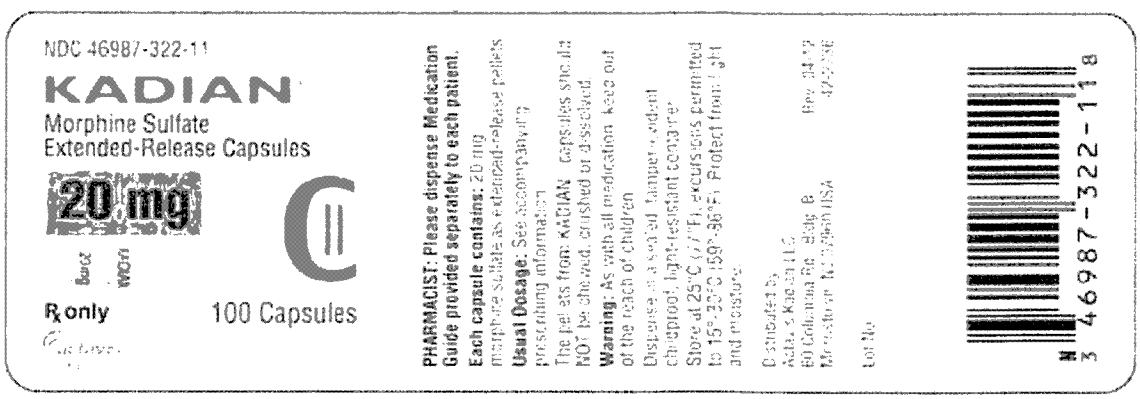
Figure 4

- Flush the empty capsule down the toilet right away (Figure 4).

You should not receive KADIAN® through a nasogastric tube.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





NDC 46987-326-11

KADIAN®

Morphine Sulfate
Extended-Release Capsules

60 mg

KADIAN

℞only

100 Capsules

actavis

PHARMACIST: Please dispense Medication Guide provided separately to each patient.

Each capsule contains: 60 mg
morphine sulfate as extended-release pellets

Usual Dosage: See accompanying prescribing information

The pellets from KADIAN® capsules should NOT be chewed, crushed or dissolved.

Warning: As with all medication, keep out of the reach of children.

Dispense in a sealed, tamper-evident, child-resistant, light-resistant container.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and moisture.

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Morristown, NJ 07960 USA

Rev. 04/12
42-2739

Lot No

3 46987-326-11 6

NDC 46987-328-11

KADIAN®

Morphine Sulfate
Extended-Release Capsules

70 mg

70 mg

KADIAN

℞only

100 Capsules

actavis

PHARMACIST: Please dispense Medication Guide provided separately to each patient.

Each capsule contains: 70 mg
morphine sulfate as extended-release pellets

Usual Dosage: See accompanying prescribing information

The pellets from KADIAN® capsules should NOT be chewed, crushed or dissolved.

Warning: As with all medication, keep out of the reach of children.

Dispense in a sealed, tamper-evident, child-resistant, light-resistant container.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and moisture.

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Morristown, NJ 07960 USA

Rev. 04/12
42-2325

Lot No

3 46987-328-11 0

NDC 46987-412-11

KADIAN®

Morphine Sulfate
Extended-Release Capsules

80 mg

80 mg

KADIAN

℞only

100 Capsules

actavis

PHARMACIST: Please dispense Medication Guide provided separately to each patient.

Each capsule contains: 80 mg
morphine sulfate as extended-release pellets

Usual Dosage: See accompanying prescribing information

The pellets from KADIAN® capsules should NOT be chewed, crushed or dissolved.

Warning: As with all medication, keep out of the reach of children.

Dispense in a sealed, tamper-evident, child-resistant, light-resistant container.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and moisture.

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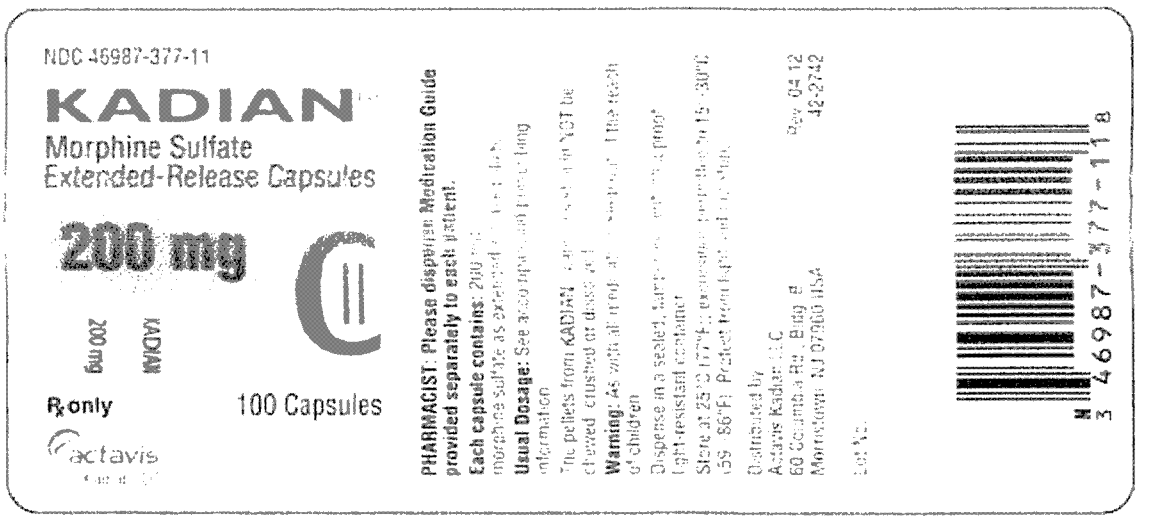
Morristown, NJ 07960 USA

Rev. 04/12
42-2740

Lot No

3 46987-412-11 6



Revised: 07/2012

Distributed by: Actavis Kadian LLC

	an additional permit as an Out-Of-State Prescription Drug Wholesale Distributor?	
8.	Are you recognized by the FDA as a manufacturer of prescription drugs? (Please select below.)	☐ Yes ☑ No
8.a	___Own Label Manufacturer ___Contract Manufacturer ___ Other:	
9.	Do you comply with all Federal and State "Current Good Manufacturing Practices?	☐ Yes ☐ No ☐ Yes ☐ No
10.	Are you located outside the United States? (If yes, provide the name of each prescription drug you intend to import into Florida and attach documentation (Example: FDA Form 2656) from the United State Food and Drug Administration (FDA) giving you approval to do so. Use additional sheets.)	☐ Yes ☑ No
11.	Are products distributed under this permit intended for export? (Note: A permit may be required for freight forwarders handling products in Florida.)	☐ Yes ☑ No
12.	Are all required records stored and maintained at applicant's physical address? (If no, provide the establishments address where all required records will be stored and maintained below.)	☑ Yes ☐ No
13.	Physical address where required records are stored Street Address:	
	City: / State: / Zip Code (+4 optional):	
14.	Are the required records computerized, automated or stored electronically? If yes, do you have a back-up procedure to be able to provide required records?	☑ Yes ☐ No ☐ Yes ☐ No
15.	Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion? (If yes, provide the types and descriptions of those systems on a separate sheet.) See Attached	☑ Yes ☐ No
16.	Is there a quarantine area at the applicant's establishment? (If not, please explain on a separate sheet.)	☐ Yes ☑ No
17.	Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's distributed products) to ensure safe storage? (If not, please explain on a separate sheet.) Corporate Office Only	☐ Yes ☑ No
18.	Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring?	☑ Yes ☐ No
19.	Have you attached a photocopy of your license/permit issued by your resident state that authorizes the sale and/or distribution of prescription drugs from the applicant address? (Note: If a license/permit is not needed in your state, you must comply with Rule 61N-1.015(6)(c), F.A.C.)	☑ Yes ☐ No

Application for a Non-Resident Prescription Drug Manufacturer
Actavis Inc.
Permit No. 261153

Question 15. Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion?

Response:

Actavis Kadian LLC is located at 60 Columbia Road, Bldg. B, Morristown, NJ 07960, which is Actavis' Corporate Headquarters, and it does not ever physically handle the drug product. Access to the facility is controlled via a state of the art Lenel CCTV and Access control system that is monitored at the facility by a receptionist during normal business hours and remotely from other Actavis facilities 24 hours a day. All exterior doors into Actavis space are equipped with an electronic access system and include keyed entry and magnetic locks. The security system has a 12-hour interim battery back up. All employees are monitored via CCTV and are issued photographic access control identification. A separate intrusion alarm system is not used at this time because the building is a shared space. However, Lenel access control system does show alarms for doors being forced open into Actavis space.

Section VIII– Qualify as a Manufacturer

QUALIFYING AS A MANUFACTURER (Check all that apply)		
1.	**Do you qualify as a "manufacturer" as a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic?**	☐ Yes ☑ No
2.	**Do you qualify as a "manufacturer" as the holder of an FDA-approved prescription drug application or biologics license?** If yes, list all biologics licenses and approved applications by number, and provide copies of no more than 5 FDA approval letters.	☐ Yes ☑ No
3.	**Do you qualify as a "manufacturer" as a private label distributor?** If yes, provide all agreements between you and any other manufacturer of a given prescription drug for which you are claiming to be a private label distributor, and a list of all NDCs and copies of all labeling for such drugs.	☑ Yes ☐ No
4.	**Do you qualify as a "manufacturer" pursuant to a co-marketing agreement or contract with another manufacturer?** If yes, provide a copy of your co-marketing agreement/contract.	☐ Yes ☑ No
5.	**Do you qualify as a "manufacturer" as an exclusive distributor for manufacturers that are members of your affiliated group as defined in Section 1504 of the Internal Revenue Code of 1986?** If yes, complete and provide the information and documents request under items A. – C. below.	☐ Yes ☑ No

A. Submit a copy of Parts I, II, and IV of the most recent Internal Revenue Service Form 851, Affiliations Schedule (Form 851) filed by the affiliated group's parent corporation, along with a copy of the certification/signature page(s) from the affiliated group's most recent consolidated tax return. If any of the information in Parts I, II or IV has changed since the Form 851 was filed, please submit a list of all such changes in the same detail required by Form 851.

B. Identify each affiliated group member identified on Form 851 above that qualifies as a "manufacturer" of prescription drugs under Section 499.003(31)(a), (b), (c) or (d), F.S. (a "source member"), and for each source member list the following:

1) Full corporate or entity name.
2) Principal place and address of business (mailing and physical).
3) State of incorporation or organization.
4) Any fictitious or trade name registered in Florida or to be used in connection with the distribution of prescription drugs in or into Florida.
5) Reference how the source member qualifies as a "manufacturer" – Section 499.003(31)(a), (b), (c) and/or (d), F.S.

C. In addition to the source members identified above, identify any other entities for which the applicant intends to distribute prescription under this permit. For each such person or entity, list the following:

1) Full corporate or entity name.
2) Principal place and address of business (mailing and physical).
3) State of incorporation or organization.
4) Any fictitious or trade name registered in Florida or to be used in connection with the distribution of prescription drugs in or into Florida.

If any entity identified in response to items B. or C. above is or was incorporated, organized or otherwise formed under the laws of any jurisdiction other than a state, possession or territory of the United States, including the District of Columbia and the Commonwealth of Puerto Rico, identify the foreign jurisdiction where each such entity was incorporated, organized or formed.

NOTE: You must advise the department in writing within (30) calendar days of any change of any

information contained or required to be contained in this source member list. This includes but is not limited to deletions and additions to source members for whom you distribute prescription drugs.

Section IX – Affidavit

AFFIDAVIT	
Each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the owner or corporate officer of the applicant without the need for witnesses unless otherwise required by law. I certify that I am empowered to execute this application as required by Section 559.79, Florida Statutes. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.	
Signature of Owner or Officer:*	Date: 10/19/12
Print Name: Terri Natzline	Title: VP, Regulatory & Medical Affairs

*** If signed by someone other than an owner or officer, you must submit a letter from an owner or officer authorizing the signer to bind the applicant.**

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399

NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0706278

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts a business at the following locations in this State:

60 COLUMBIA RD - BLDG B MORRISTOWN, NJ 07960-

Reg. No.
5003872

ACTAVIS INC
ACTAVIS KADIAN LLC
60 COLUMBIA RD - BLDG B
MORRISTOWN, NJ 07960-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2013

Establishment Copy

ACTAVIS KADIAN LLC
STATE AND FEDERAL CORPORATE REGISTRATIONS

STATE/AGENCY	BUSINESS ACTIVITY	PERMIT NO.	EXPIRATION DATE
Alabama	Rx DRUGS & CDS	193945	12/31/2012
	CDS	193945	12/31/2012
Arkansas	Rx DRUGS & CDS	WD03785	12/31/2012
Florida	Rx DRUGS & CDS	26 1153	9/30/2012
Iowa	Rx DRUGS & CDS	6990	12/31/2012
Louisiana	Rx DRUGS	6701	12/31/2012
Minnesota	Rx DRUGS & CDS	362435	5/31/2013
Montana	Rx DRUGS & CDS	2990	11/30/2013
New Hampshire	Rx DRUGS & CDS	5140	6/30/2013
New Jersey	Rx DRUGS	5003872	1/31/2012
New Mexico	Rx DRUGS	WD00011156	12/31/2013
	CDS	CS00215575	6/30/2013
New York	Rx DRUGS	31014	10/31/2014
	CDS	01A0231	10/1/2014
North Carolina	Rx DRUGS	522	12/31/2012
North Dakota	Rx DRUGS & CDS	319	6/30/2013
Ohio	Rx DRUGS	12120650	6/30/2013
	CDS	2542	6/30/2013
Oklahoma	Rx DRUGS & CDS	88-W-2631	10/31/2013
Oregon	Rx DRUGS & CDS	M-0002090-CS	9/30/2013
South Dakota	Rx DRUGS	600-1710	12/31/2012
Texas	Rx DRUGS & CDS	1000455	8/3/2014

52150 DEPARTMENT OF BUSINESS & 322556

Invoice	Inv Date	Remarks	Net Amount
CKRQ102212	10/22/12		1,000.00
			1,000.00

DO NOT CASH THIS CHECK WITHOUT VERIFYING SECURITY FEATURES ON BACK OF CHECK

actavis

200 ELMORA AVE.
ELIZABETH, NJ 07207

CHECK NUMBER: 322556 10/25/12

Wells Fargo

USD ********1,000.00

One Thousand Dollars And No Cents

PAY TO THE ORDER OF:

DEPARTMENT OF BUSINESS &
PROFESSIONAL REGULATION
1940 NORTH MONROE STREET
TALLAHASSEE, FL 32399
UNITED STATES

Stephen Gallagher
AUTHORIZED SIGNATURE

WARM AREA TO REVEAL WORD "VALID"

⑈322556⑈ ⑆031100225⑆ 2079951076361⑈

ACTAVIS INC. CHECK REQUEST

Checks to be issued on Friday

Make Check Payable to:	
Name	**Florida Department of Business and Professional Regulation**
Address	1940 North Monroe Street
City	Tallahassee
State, Zip	FL, 32399
Phone	850-245-4292

Amount -$	1,000.00
Dept. and Cacti or Capex No.	98-35575-705

Reason Explain in Detail	Florida – Change of Ownership Rx Drugs & CDS application for Actavis Kadian LLC See attached
SPECIAL HANDLING INSTRUCTIONS	Please return to Silvia Sanles/Morristown

Originated By:	SILVIA SANLES
	Signature: [signature]
	Date: 10/19/12 Ext.: 1256960

Approved By:	TERRI NATALINE
	Signature: [signature]
	Date: 10/19/12 Ext.: 1202317

Approved By:	
Finance Review	Signature:
	Date: Ext.
Please attach all supporting documents. Invoices, Quotes, Proof of Delivery, etc.	

AC# 4052233

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
09/16/2010	**26 1153**	**2146**

The **NON-RESIDENT RX DRUG MANUFACTURER**
named below has met all requirements of
the laws and rules of the state of Florida.

Expiration Date: **SEPTEMBER 30, 2012**

ACTAVIS KADIAN LLC
60 COLUMBIA RD
BLDG-B
MORRISTOWN, NJ 07960

Charlie Crist
GOVERNOR

Ana M. Viamonte Ros, M.D., M.P.H.
STATE SURGEON GENERAL

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

AC# 4052233

DATE	LICENSE NO.	CONTROL NO.
09/16/2010	26 1153	2146

The **NON-RESIDENT RX DRUG MANUFACTURER** named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: **SEPTEMBER 30, 2012**

ACTAVIS KADIAN LLC

LICENSEE SIGNATURE

EXPIRATION DATE: **SEPTEMBER 30, 2012**

Your license number is **26 1154**. please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the department in writi the licensee's current mailing address and practice location address. Use this section to report mailing address changes.

Medical Quality Assurance offers you the convenience of several online services. These services give you the ability to update your mailing address.

1. Go to **www.flhealthsource.com**
2. Click on Licensee/Provider
3. Click on Practitioner Login
4. Select your profession
5. Enter the account ID and password here **(Account ID and Password are case sensitive)** Account ID: **actavi14** Password: **5Xc55CC7**
   Where '1' is number ONE.
6. Click on Login

Your opinion is important to us. To help us continue to improve our customer service, please take a moment to complete our online survey about the kind of service we provided you in obtaining your license. **http://www.doh.state.fl.us/mqa/Surveys/new-lic.htm** Thank you for helping us better serve you and our other customers.

MAIL TO: **DEPARTMENT OF HEALTH**
DIVISION OF MEDICAL QUALITY ASSURANCE
LICENSING AND AUDITING SERVICES UNIT
P.O. BOX 6320
TALLAHASSEE, FLORIDA 32314-6320

DH 2103 5/98

AC# 405 1233

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
09/16/2010	26 1153	2146

The **NON-RESIDENT RX DRUG MANUFACTURER**
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: **SEPTEMBER 30, 2012**

ACTAVIS KADIAN LLC
60 COLUMBIA RD
BLDG-B
MORRISTOWN, NJ 07960

Charlie Crist
GOVERNOR

Ana M. Viamonte Ros, M.D., M.P.H.
STATE SURGEON GENERAL

DISPLAY IF REQUIRED BY LAW

Silvia Sanles

From: Silvia Sanles
Sent: Friday, August 13, 2010 9:51 AM
To: 'Rebecca_Burnett@doh.state.fl.us'
Subject: RE: Actavis Inc. - Florida Registration Requirement

Attachments: Applicant ID# 6511-Actavis Inc.; Applicant ID# 6509-Actavis Kadian LLC; Applicant ID # 6510 - Actavis India Location


Applicant ID# 6511-Actavis Inc...


Applicant ID# 6509-Actavis Kad...


Applicant ID # 6510 - Actavis ...

Good Morning Rebecca,
Attached are the 3 e-mails sent to Shannon on June 17, 2010, with regards to Actavis' pending applications.

Your assistance is greatly appreciated. Thank you and have a great weekend.

Regards,
Silvia
-----Original Message-----
From: Rebecca_Burnett@doh.state.fl.us [mailto:Rebecca_Burnett@doh.state.fl.us]
Sent: Friday, August 13, 2010 9:47 AM
To: Silvia Sanles
Subject: RE: Actavis Inc. - Florida Registration Requirement

Good Morning Silvia,

If you submitted information to Shannon via email, please forward that information to me for review.

Thanks
Rebecca

-----Original Message-----
From: Silvia Sanles [mailto:SSanles@actavis.com]
Sent: Thursday, August 12, 2010 8:30 AM
To: Burnett, Rebecca J
Subject: RE: Actavis Inc. - Florida Registration Requirement

Good Morning Rebecca,

Thanks for the confirmation.

Actavis Inc's Non-Resident application was submitted on May 18, 2010 and is pending approval, can you please provide a status.

Shannon was reviewing our applications (for Actavis Inc. & Actavis Kadian LLC) and requested further information via e-mail on July 17, 2010, however, she is no longer with the Department of Health.

Thanks again for your assistance.

Regards,

Silvia
-----Original Message-----
From: Rebecca_Burnett@doh.state.fl.us
[mailto:Rebecca_Burnett@doh.state.fl.us]
Sent: Wednesday, August 11, 2010 4:23 PM
To: Silvia Sanles
Subject: RE: Actavis Inc. - Florida Registration Requirement

Good Afternoon Silvia,

A private label distributor fall under Florida's definition of manufacturer. However, if you distribute any products that are not privately labeled for your company, another permit may be required in addition to the manufacturer permit.

Rebecca

-----Original Message-----
From: Silvia Sanles [mailto:SSanles@actavis.com]
Sent: Thursday, August 05, 2010 10:37 AM
To: Burnett, Rebecca J
Subject: RE: Actavis Inc. - Florida Registration Requirement

Dear Rebecca,
I wanted to follow up with regards to my previose e-mail (see below).

If you have any further questions please contact me at (973) 889-6960.

Thank you.

Regards,
Silvia

From: Silvia Sanles
Sent: Tue 7/27/2010 8:41 AM
To: 'Rebecca_burnett@doh.state.fl.us'
Cc: Silvia Sanles
Subject: Actavis Inc. - Florida Registration Requirement

Dear Rebecca,

As per our conversation on July 26, 2010, below is a description of Actavis Inc.'s operations:

Actavis Inc.:

* Is a private-label & own-label distributor
* Does not ever handle the drug product(s)
* Ships product(s) directly from a manufacturer to the 3rd Party Logistics Provider for distribution under the Actavis Inc. name.
* Product Labeling says Distributed by: Actavis Inc. or Manufactured for: Actavis Inc.
* Does not purchase product(s) from a manufacturer or wholesaler

and re-sales or re-packages.

Your assistance in determining the appropriate Florida Registration for Actavis Inc. is greatly appreciated, thank you.

Regards,

Silvia Sanles
Supervisor, Regulatory Affairs

Actavis
60 Columbia Rd. Bldg B t +1 973-889-6960 @ SSanles@actavis.com
Morristown , NJ 07960 United States w www.actavis.com
<http://www.actavis.com/>
Internal VoIP number t 1256960

Silvia Sanles

From: Silvia Sanles
Sent: Thursday, June 17, 2010 2:04 PM
To: Shannon_Elliott@doh.state.fl.us
Subject: Applicant ID# 6509-Actavis Kadian LLC
Attachments: FL-Response to Deficiency Question 3.DOC; 46987-323-11 50 mg 100's Kadian.pdf; 40-9101 KADIAN (Morphine Sulfate Extended-Release) Capsules Rev. 2-10.pdf; 46987-326-11 60 mg 100's Kadian.pdf; 46987-324-11 100 mg 100's Kadian.pdf; 46987-322-11 20 mg 100's Kadian.pdf; 46987-412-11 80 mg 100's Kadian.pdf; 46987-377-11 200 mg 100's Kadian.pdf; 46987-325-11 30 mg 100's Kadian.pdf; FL-DEFICIENCY KADIAN.pdf; FDA REGISTRATION-LABELER CODE.pdf

Dear Shannon,
As per our conversation earlier today and with response to deficiency letter dated June 8, 2010 (for your reference attached is a copy of the letter), attached please copies of our drug product labeling and our response to Question No. 3.

As I previously stated, FDA does not register private-label distributors, it only provides a labeler code. Attached is confirmation that labeler code No. 46987 corresponds with Actavis Kadian LLC. You can access this information by going to the FDA website:
http://www.accessdata.fda.gov/scripts/cder/ndc/queryndcfn.cfm.

Please contact me directly should you have any questions or need additional information.

Regards,

Silvia Sanles
Supervisor, Regulatory Affairs

actavis
creating value in pharmaceuticals

Actavis
60 Columbia Rd. Bldg B *t* +1 973-889-6960 @ SSanles@actavis.com
Morristown , NJ 07960 United States *w* www.actavis.com
Internal VoIP number *t* 1256960

NDC Search Results on Actavis Kadian LLC

Firm Name	Labeler Code
ACTAVIS KADIAN LLC	46987

Return to National Drug Code Directory Home Page

FLORIDA DEPARTMENT OF HEALTH

Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., MPH
State Surgeon General

June 8, 2010

Actavis Inc. — Actavis Kadian LLC
60 Columbia Rd
Bldg- B
Morristown NJ 07960

RE: Applicant ID#: 6509

Dear Applicant:

Thank you for submitting your application and fees to the Drugs, Devices, & Cosmetics Program. Listed below are the following items needed to complete your application.

1. The Manufacturers application requires an FDA establishment registration number or a copy of the application you submitted to the FDA.

2. Submit a copy of your labels.

3. Please clarify why you don't need a DEA#.

Provide the incomplete information and return to us by mail or fax within thirty-days (30). If you have any additional questions, you may contact me at the address listed below, by telephone at 850-245-4444 ext. 3866 or by e-mail at Shannon_elliott@doh.state.fl.us.

Sincerely,

Shannon Elliott
Shannon Elliott
Regulatory Specialist II

FLORIDA DRUGS, DEVICES AND COSMETICS PROGRAM
4052 Bald Cypress Way, Bin C04
Tallahassee, FL 32399-3258
http://www.doh.state.fl.us

Silvia Sanles

From: Shannon_Elliott@doh.state.fl.us
To: Silvia Sanles
Sent: Thursday, June 17, 2010 2:08 PM
Subject: Read: Applicant ID# 6509-Actavis Kadian LLC

Your message

To: Shannon_Elliott@doh.state.fl.us
Subject:

was read on 6/17/2010 2:08 PM.

Silvia Sanles

From: Shannon_Elliott@doh.state.fl.us
Sent: Wednesday, May 26, 2010 1:43 PM
To: Silvia Sanles
Subject: RE: Initial Application for Actavis Inc.

Thank you I will, I have not been able to review your applications yet but I should be able to very soon.
Thanks

Thanks,

Shannon Elliott, Regulatory Specialist II, DDC Program
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399
(850) 245-4292 ext.3866 fax: (850) 413-6982
Drugs, Devices, and Cosmetics Program: www.doh.state.fl.us/mqa/ddc

We would like to hear from you. Please take a few minutes to contact my supervisor Rebecca Burnett at Rebecca_Burnett@doh.state.fl.us ***about the quality of service you received. The Department of Health values your feedback as a customer. The Dept of Health values your feedback as a customer. Please take a few minutes to complete our customer service survey at http://survey.doh.state.fl.us/survey/entry.jsp?id=1224772782379***

The mission of the Department of Health is to promote, protect and improve the health of all people in Florida. Our vision is a healthier future for the people of Florida. MQA's purpose is to protect the public through health care licensure, enforcement and information and our focus is to be the nation's leader in quality health care regulation.

From: Silvia Sanles [mailto:SSanles@actavis.com]
Sent: Wednesday, May 26, 2010 9:52 AM
To: Porter, Trisha; Elliott, Shannon
Subject: RE: Initial Application for Actavis Inc.

Trisha,
Thanks for all your help and for the update.

Shannon,
If you have any questions or comments with regards to our applications for Actavis Pharma Mfr Pvt Ltd, Actavis Inc. and Actavis Kadian LLC, please contact me directly.

Thank you in advance.

Regards,

Silvia Sanles
Supervisor, Regulatory Affairs

actavis
creating value in pharmaceuticals

Actavis
60 Columbia Rd. Bldg B *t* +1 973-889-6960 @ SSanles@actavis.com

6/7/2010

Morristown , NJ 07960 United States w www.actavis.com
Internal VoIP number t 1256960

From: Trisha_Porter@doh.state.fl.us [mailto:Trisha_Porter@doh.state.fl.us]
Sent: Tuesday, May 25, 2010 8:00 AM
To: Silvia Sanles
Cc: Shannon_Elliott@doh.state.fl.us
Subject: RE: Initial Application for Actavis Inc.

Dear Ms. Sanles:

Your application was received by the Department but I will not be the processor. The application will be processed by Shannon Elliott.

I am CC: her on this response.

Please note we process all application in date order so it will be a few weeks before your application will be reviewed. Thanks.

Trisha S. Porter, RS-II
Drugs, Devices and Cosmetic Program
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254
Telephone: (850) 245-4444 Ext. 3601
Fax: (850) 617-6429
Email: Trisha_Porter@doh.state.fl.us
Website: **www.doh.state.fl.us/mqa/ddc**
The Dept of Health values your feedback as a customer.
Please take a few minutes to complete our customer service survey at:
http://survey.doh.state.fl.us/survey/entry.jsp?id=1224772782379
Mission: Promote, protect and improve the health of all people in Florida.
Vision: A healthier future for the people of Florida.
Purpose: Protect the public through health care licensure, enforcement and info.
Focus: To be the nation's leader in quality health care regulation.
Contact my Supervisor: Rebecca Burnett at Rebecca_Burnett@doh.state.fl.us

From: Silvia Sanles [mailto:SSanles@actavis.com]
Sent: Monday, May 24, 2010 10:54 AM
To: Porter, Trisha
Subject: Initial Application for Actavis Inc.

Trisha,
An initial application for **Actavis Inc.** was mailed to your attention on May 18, 2010. At that time our New Jersey Rx Drug permit was not issued, thus we didn't include with the application. We have received our license, attached is a copy for your files.

Please amend our application. Thank you.

Regards,
Silvia Sanles
Supervisor, Regulatory Affairs

6/7/2010

Actavis
60 Columbia Rd. Bldg B *t* +1 973-889-6960 @ SSanles@actavis.com
Morristown , NJ 07960 United States *w* www.actavis.com
Internal VoIP number *t* 1256960

For up-to-date information about H1N1 Swine Flu visit http://www.myflusafety.com ***or call 877 352 3581***

For up-to-date information about H1N1 Swine Flu visit http://www.myflusafety.com ***or call 877 352 3581***

ACTAVIS ELIZABETH LLC

ACCOUNT NUMBER	INVOICE NUMBER RETURNS - CR.	DATE MO.	DATE DAY	DATE YEAR	INVOICE AMOUNT	DISCOUNT	NET AMOUNT
	REF040510	04	05	10	1000.00	0.00	1000.00
					1000.00	0.00	1000.00

- DETACH BEFORE DEPOSITING -

actavis
creating value in pharmaceuticals

VIA UPS OVERNIGHT MAIL

May 18, 2010

Mrs. Trisha Porter
Florida Department of Health
Board of Pharmacy
Drugs, Devices & Cosmetics
4052 Bald Cypress Way
Tallahassee, FL 32314-6320

RE: Initial Application
Actavis Kadian LLC

Dear Trisha:

Enclosed please find our completed Non-Resident Prescription Drug Manufacturer application for Actavis Kadian LLC. Please note that Actavis is a private label distributor who does not handle, distribute or sell the drug product into Florida.

For your reference, attached please find copies of our drug product labeling for Kadian® Oral Capsule ER.

If you have any questions or require any additional information, please contact me at 973-889-6960.

Sincerely yours,
ACTAVIS KADIAN LLC

Silvia Sanlés
Supervisor, Regulatory Affairs

SS
Encls.

Actavis Inc. | 60 Columbia Rd., Bldg. B Morristown, NJ 07960 | t (973) 993-4501 | www.actavis.com

Silvia Sanles

From: UPS Quantum View [auto-notify@ups.com]
Sent: Wednesday, May 19, 2010 10:15 AM
To: Silvia Sanles
Subject: UPS Delivery Notification, Tracking Number 1Z457FV90199350360

***Do not reply to this e-mail. UPS and Actavis INC. will not receive your reply.

At the request of Actavis INC., this notice is to confirm that the following shipment has been delivered.

Important Delivery Information

Message from Actavis INC.:
Non-Resident Applications for: Actavis Inc , Actavis Kadian LLC and Actavis Pharma Manufacturing Pvt. Ltd

Delivery Date / Time: 19-May-2010 / 9:46 AM
Delivery Location Left At: PHARMACY
Signed by: LESLEY

Shipment Detail

Ship To:
Mrs. Trisha Porter
Florida Department of Health
4052 BALD CYPRESS WAY
TALLAHASSEE
FL
32399
US

UPS Service: NEXT DAY AIR
Shipment Type: Letter

Tracking Number: 1Z457FV90199350360
Reference Number 1: Actavis Inc., Actavis Kadian LLC &
Reference Number 2: Actavis Pharma Pvt Ltd-Applications

____2rr2rr2k8luKbm____

Discover more about UPS:
Visit www.ups.com
Sign Up For Additional E-Mail From UPS

5/19/2010

UPS Internet Shipping: View/Print Label

1. **Print the label(s):** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.

2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**
   Customers without a Daily Pickup
   - Schedule a same day or future day Pickup to have a UPS driver pickup all of your Internet Shipping packages.
   - Hand the package to any UPS driver in your area.
   - Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return Services℠ (including via Ground) are also accepted at Drop Boxes.
   - To find the location nearest you, please visit the 'Find Locations' Quick link at ups.com.

   Customers with a Daily Pickup
   - Your driver will pickup your shipment(s) as usual.

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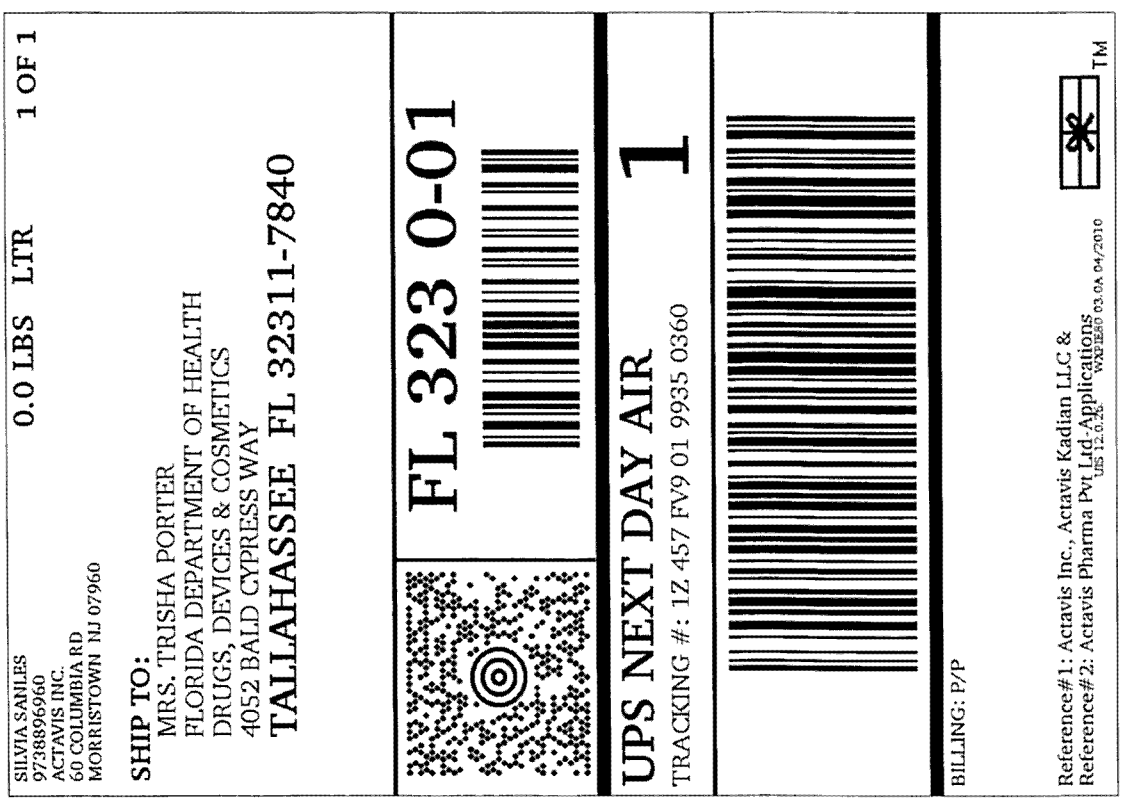


APPLICATION FOR A PERMIT UNDER CHAPTER 499, FLORIDA STATUTES

FLORIDA DEPARTMENT OF HEALTH

Florida Department of Health Drugs, Devices and Cosmetics
P.O. Box 6320 - Tallahassee, Florida 32314-6320 (850) 245-4292

This application form provides information as required by the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes. Only a completed application signed by the authorized representative of the applicant will be processed. Additional information may be required for an application to be considered complete.

This application must be filled out in its entirety. Failure to do so will result in a delay in the permitting process.

APPLICATION TO BE TYPED OR PRINTED WITH INK

Mark an "X" on the line for the type of permit(s) that apply. The applicant can apply for multiple permits under one application if each permit requested is at the same physical address and the same permit name. **DO NOT USE this application to apply for a Prescription Drug Wholesale Distributor, Prescription Drug Wholesale Distributor/Broker Only, or Out-of-State Prescription Drug Wholesale Distributor permit; use form DH 2124**

MANUFACTURERS

- ___ Prescription Drug Manufacturer
- ___ Over-the-Counter Drug Manufacturer
- ___ Device Manufacturer
- ___ Compressed Medical Gas Manufacturer
- X Non-resident Prescription Drug Manufacturer

RESTRICTED PERMITS

- ___ Restricted Prescription Drug Distributor - Health Care Entity
- ___ Restricted Prescription Drug Distributor - Charitable Organization
- ___ Restricted Prescription Drug Distributor - Reverse Distributor
- ___ Restricted Prescription Drug Distributor - Destruction
- ___ Restricted Prescription Drug Distributor - Government Programs
- ___ Restricted Prescription Drug Distributor - Institutional Research

WHOLESALE DISTRIBUTORS

- ___ Compressed Medical Gas Wholesale Distributor
- ___ Limited Prescription Drug Veterinary Wholesale Distributor
- ___ Retail Pharmacy Drug Wholesale Distributor
- ___ Veterinary Prescription Drug Wholesale Distributor

OTHER DISTRIBUTORS

- ___ Complimentary Drug Distributor
- ___ Freight Forwarder
- ___ Medical Oxygen Retail Establishment
- ___ Prescription Drug Repackager
- ___ Third Party Logistics Provider (3PL)
- ___ Veterinary Prescription Drug Retail Establishment

1 NAME OF APPLICANT (name in which company is doing business; this is the name in which the permit will be issued; limit to 41 characters)
Actavis Kadian LLC

2 APPLICANT ADDRESS (physical location of establishment - this address shall be reflected on all sales invoices and shipping documentation)
60 Columbia Rd

3 SUITE NUMBER
Bldg B

4 CITY
Morristown

5 STATE
NJ

6 ZIP
07960 -

7 COUNTY
Morris

8 AREA CODE & TELEPHONE NUMBER
973 - 993 - 4501

9 *BUSINESS OPERATING HOURS

M	8	: 30	AM PM	TO 5	: 00	AM PM
TU	8	: 30	AM PM	TO 5	: 00	AM PM
W	8	: 30	AM PM	TO 5	: 00	AM PM
TH	8	: 30	AM PM	TO 5	: 00	AM PM
F	8	: 30	AM PM	TO 5	: 00	AM PM

10 *PROVIDE AN EMAIL ADDRESS WHERE REGULATORY UPDATES CAN BE SENT
SSanles@actavis.com

11 *FACSIMILE NUMBER WHERE REGULATORY UPDATES CAN BE SENT
973 - 993 - 4308

*NOTIFY THE DEPARTMENT IN WRITING OF ANY CHANGES.

12 MAILING ADDRESS (if different from physical location; this is where the renewal application and other official information will be sent by the department)
Same as Above

13 SUITE NUMBER

14 CITY

15 STATE

16 ZIP -

17 EMERGENCY CONTACT PERSON (an individual with your company that the department can contact, if necessary, after normal business hours)

NAME (Last, First, MI)
Young, Christopher, C.

RESIDENCE PHONE (Area Code & Number)
732 - 530 - 0874

RESIDENCE ADDRESS
29 Stag Place

POSITION/TITLE
VP, OS Operations

CITY
Lincroft

STATE
NJ

ZIP CODE
07738 -

OFFICE USE ONLY

APPLICATION REVIEW	INSPECTION	PERMIT ISSUED OR DENIED
Approved by: _____	Inspected By: _____	Permit No: _____
Date: _____	Date: _____	Expiration Date: _____
Fee: _____	Is follow up required? _____	Denied by: _____ Date _____

18 PROVIDE FEDERAL TAX IDENTIFICATION NUMBER)#) If you do not have an FEID#, call 1-800-829-1

26-4049920

19 PROVIDE CORPORATE OR LEGAL NAME OF BUSINESS ENTITY IF DIFFERENT FROM APPLICANT NAME:

N/A

20 IDENTIFY BY NAME AND ADDRESS EACH PERSON WHO WILL PARTICIPATE IN ADMINISTERING OR OPERATING THE ESTABLISHMENT.

NAME (Last, First, MI)	ADDRESS	CITY	STATE
See Attached			

21 MARK AN "X" ON THE LINE FOR THE TYPE OF OWNERSHIP. (Mark only **ONE** in this section [shaded areas] and provide all necessary information as requested):

A. ___ **SOLE PROPRIETORSHIP**

LIST OWNER'S NAME (Last, First, MI) DATE OF BIRTH (mm/dd/yy) ___/___/___

B. ___ **PARTNERSHIP**

LIST ALL PARTNERS (use additional sheet if necessary) NAME (Last, First, MI)	DATE OF BIRTH (mm/dd/yy)	TITLE (if applicable)	% OF OWNERSHIP (must total to 100%)
	___/___/___		%
	___/___/___		%
	___/___/___		%
	___/___/___		%
	___/___/___		%

C. ___ **PUBLICLY HELD CORPORATION OR** ___ **CLOSELY HELD CORPORATION**
(traded on a stock exchange)

Provide a listing of each individual, other than the officers listed below, (if applicable) holding 5% or more of the corporation's voting stock. Include names, dates of birth and percentage of ownership.

STATE OF INCORPORATION _____ (state abbreviation) LIST THE REGISTERED AGENT OF THE CORPORATION _____

ARE **ALL** CORPORATE OFFICERS EIGHTEEN (18) YEARS OF AGE OR OLDER? ___ YES ___ NO

IS THE APPLICANT A SUBSIDIARY OF ANOTHER COMPANY? ___ YES ___ NO If **yes**, provide a listing of all parent companies with percentages of ownership. Please note: A permit issued pursuant to this applicant is only valid for the applicant's name and address.

LIST THE FIVE MOST SENIOR CORPORATE OFFICERS (i.e., CEO/COO, President, V.P., Sec., Treas.): (use additional sheet if necessary)

NAME (Last, First, MI)	DATE OF BIRTH (mm/dd/yy)	POSITION/TITLE	% OF OWNERSHIP
	___/___/___		% if applicable
	___/___/___		% if applicable
	___/___/___		% if applicable
	___/___/___		% if applicable
	___/___/___		% if applicable

D. X **LIMITED LIABILITY COMPANY (LLC)**

LIST THE NAME AND ADDRESS OF THE LLC, THE REGISTERED AGENT OF THE LLC, AND THE NAME OF THE STATE IN WHICH THE LLC WAS ORGANIZED BELOW:

NAME OF THE LLC	ADDRESS	CITY	STATE
Actavis Kadian LLC	60 Columbia Rd, Bldg B	Morristown	NJ

LIST THE REGISTERED AGENT OF THE LLC: See Attached

NAME OF THE STATE IN WHICH THE LLC WAS ORGANIZED: _____ (state abbreviation)

LIST THE NAME AND ADDRESS OF EACH MEMBER (Use an additional sheet if necessary)

NAME (Last, First, MI)	ADDRESS	CITY	STATE	% OF OWNERSHIP
				% if applicable
				% if applicable
				% if applicable
				% if applicable
				% if applicable

E. ___ **OTHER (Explain)**

F. ___ **GOVERNMENT**

22 HAS THE APPLICANT, OWNER(S), MANAGER(S)-IN-CHARGE, ANY OFFICER(S) AND/OR EMPLOYEES:

A. BEEN FINED OR DISCIPLINED BY A REGULATORY AGENCY IN ANY STATE (INCLUDING FLORIDA) FOR ANY OFFENSE THAT WOULD CONSTITUTE A VIOLATION OF CHAPTER 499, F.S.? ___YES X NO

B. EVER ENTERED A PLEA TO, BEEN CONVICTED OR FOUND GUILTY OF, ANY FELONY UNDER A FEDERAL, STATE (INCLUDING FLORIDA), OR LOCAL LAW? INCLUDE ALL CASES WHERE A GUILTY, NOLO CONTENDERE OR NO CONTEST PLEA WAS ENTERED, WHETHER OR NOT ADJUDICATION WAS WITHHELD. ___YES X NO

C. HAD ANY CURRENT OR PREVIOUS PERMIT OR LICENSE SUSPENDED OR REVOKED WHICH WAS ISSUED BY A FEDERAL, STATE OR LOCAL GOVERNMENTAL AGENCY RELATING TO THE MANUFACTURE OR DISTRIBUTION OF DRUGS, DEVICES, OR COSMETICS? ___YES X NO

D. BEEN DENIED A PERMIT OR LICENSE RELATED TO AN ACTIVITY REGULATED UNDER CHAPTER 499, F.S., IN ANY STATE? ___YES X NO

E. EVER HELD A PERMIT ISSUED UNDER CHAPTER 499, F.S., IN A DIFFERENT NAME THAN THE APPLICANT'S NAME? IF YES, PROVIDE THE NAMES IN WHICH EACH PERMIT WAS ISSUED AND AT WHAT ADDRESS. ___YES X NO

Name: _____ Address: _____

IDENTIFY BY NAME, DATE OF BIRTH, ADDRESS AND POSITION WITH THE COMPANY, ANY PERSON THAT IS THE SUBJECT OF A "YES" RESPONSE TO ANY OF THE QUESTIONS A. THROUGH E. IMMEDIATELY ABOVE. FOR ALL CRIMINAL CASES, PROVIDE COURT CHARGING DOCUMENTS AND FINAL DISPOSITION DOCUMENTS, INCLUDING ANY JUDGMENT, SENTENCE OR PLEA DOCUMENTS. PROVIDE A COPY OF ANY ORDER THAT FINED, DISCIPLINED, REVOKED, SUSPENDED, OR DENIED ANY LICENSE/PERMIT TO MANUFACTURE OR DISTRIBUTE DRUGS, DEVICES OR COSMETICS ISSUED BY ANY GOVERNMENT AGENCY. PROVIDE A DETAILED EXPLANATION OF THE CIRCUMSTANCES INVOLVED WITH EACH "YES" RESPONSE TO ANY OF THE QUESTIONS A. THROUGH E. IMMEDIATELY ABOVE.

23 ARE THERE ANY OTHER PERMITS (FOR PHARMACIES OR LICENSES FOR PRACTITIONERS) ISSUED BY ANY AGENCY IN THE STATE OF FLORIDA THAT AUTHORIZE THE PURCHASE OR POSSESSION OF PRESCRIPTION DRUGS AT THE APPLICANT'S ADDRESS? ___YES X NO

If yes, provide the name in which the permit is issued, the permit type and permit number.

Name: _____ Address: _____ Permit Number: _____

24 CHECK THE APPROPRIATE BOX(ES) FOR THE TYPE OF PRODUCT(S) YOU WILL HANDLE USING THE PERMIT(S) FOR WHICH YOU ARE APPLYING:

X Human Prescription Drugs ___Veterinary Prescription Drugs ___OTC Drugs ___Oxygen ___Other Gases ___Cosmetics ___Medical Devices

X Controlled Substances (mark all that apply) X SCH II ___SCH III ___SCH IV ___SCH V PROVIDE YOUR DEA# N/A-facility does not handle the product

25 TO WHOM DO YOU INTEND TO DISTRIBUTE YOUR PRODUCT(S) UNDER THE PERMIT(S) FOR WHICH YOU ARE APPLYING?

___Manufacturers X Wholesale Distributors ___Pharmacies ___Hospitals ___Clinics ___Healthcare Practitioners ___Public

___Patients with a Prescription ___Veterinarians ___Other Drug Chain Warehouses/Distribution Centers, Repackers, Mail Order Accounts, Nursing Home Providers & Managed Care Organizations.

26 TYPE OF SALES: X Domestic (USA) ___Export

27 WHERE WILL THE REQUIRED RECORDS BE STORED AND MAINTAINED? X Applicant Address ___Other Physical Address (Explain):

28 ARE YOUR RECORDS MAINTAINED IN AN ELECTRONIC FORMAT? X YES ___NO

29 THE CONTENT OF AN ELECTRONICALLY MAINTAINED RECORD MUST BE IDENTICAL TO THE CONTENT OF THE ORIGINAL RECORD AS CREATED. DO YOU UNDERSTAND ELECTRONICALLY MAINTAINED RECORDS CANNOT BE UPDATED? X YES ___NO

30 DOES THE APPLICANT AGREE TO COMPLY WITH CHAPTER 499, FLORIDA STATUTES, AND RULE CHAPTER 64F-12, FLORIDA ADMINISTRATIVE CODE? X YES ___NO

31 DOES THE APPLICANT UNDERSTAND THAT YOU CANNOT BEGIN OPERATIONS IN OR INTO FLORIDA UNTIL A PERMIT HAS BEEN ISSUED? X YES ___NO

32 DOES THE APPLICANT CURRENTLY OR HAVE AT ANYTIME HAD OWNERSHIP INTEREST IN OTHER COMPANIES? ___YES X NO
If yes, provide a list of all companies.

33 IS THIS NEW APPLICATION RELATED TO A CHANGE OF OWNERSHIP? If yes, provide change of ownership documentation. ___YES X NO
If yes, please include the permit number of the current holder. Permit Number: _____

34 WHO SHOULD THE DEPARTMENT CONTACT WITH QUESTIONS REGARDING THIS APPLICATION?

NAME (Last, First, MI) Sanles, Silvia AREA CODE & TELEPHONE NUMBER 973 - 889 - 6960 POSITION/TITLE Sup., Reg. Affairs

ADDRESS 60 Columbia Rd, Bldg B

CITY Morristown STATE NJ ZIP CODE 07960 -

EMAIL ADDRESS SSanles@actavis.com FACSIMILE NUMBER (fax) 973 - 993 - 4308

35 COMPLETE THE QUESTIONS ON THE ATTA ENTS RELATED TO THE SPECIFIC PERMITS FO HICH YOU ARE APPLYING.

MANUFACTURER (Prescription Drug, Over-the-Counter Drug, Device, Cosmetic)

LIMITED PRESCRIPTION DRUG VETERINARY WHOLESALE DISTRIBUTOR

NON-RESIDENT PRESCRIPTION DRUG MANUFACTURER

PRESCRIPTION DRUG REPACKAGER

MEDICAL GASES (Compressed Medical Gas Manufacturer, Compressed Medical Gas Wholesale Distributor, Medical Oxygen Retailer)

RESTRICTED PRESCRIPTION DRUG DISTRIBUTOR- HEALTH CARE / CHARITABLE ORGANIZATION / GOVERNMENT PROGRAMS / INSTITUTIONAL RESEARCH

RESTRICTED - REVERSE DISTRIBUTOR / DESTRUCTION

RETAIL PHARMACY DRUG WHOLESALE DISTRIBUTOR

COMPLIMENTARY DRUG DISTRIBUTOR

THIRD PARTY LOGISTICS PROVIDER (3PL)

VETERINARY PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR

VETERINARY PRESCRIPTION DRUG RETAIL ESTABLISHMENT

AFFIDAVIT:

(must be completed and notarized)

I, Terri Nataline (Print Name) ON BEHALF OF THE APPLICANT BUSINESS, DO SOLEMNLY SWEAR AND AFFIRM THAT THE INFORMATION SUBMITTED TO THE DEPARTMENT ON THIS APPLICATION AND ANY ATTACHMENTS THERETO ARE TRUE AND CORRECT.

Terri Nataline — **Signature of Owner or Company Officer**

VP, Regulatory & Medical Affairs — **Title**

04/08/10 — **Date**

If signed by someone other than an owner or officer identified in question #21, you must submit a letter of delegation for the signer to bind the applicant.

NOTARY STAMP OR SEAL

State of New Jersey

County of Morris

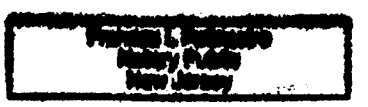
The foregoing instrument was sworn to before me this 8th day of April, 2010

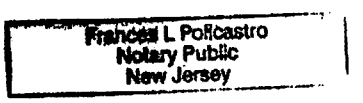
He/She is ✓ personally know to me or produced _____ as identification.

Notary Public (Sign Name Here): Frances L. Policastro

Notary Public (Print Name Here): Frances L. Policastro

2324594 - 1/31/2015 — Commission No. & Expiration Date





NON-RESIDENT PRESCRIPTION DRUG MANUFACTURER

IF THE APPLICANT IS APPLYING FOR A NON-RESIDENT PRESCRIPTION DRUG MANUFACTURER PERMIT, YOU MUST COMPLETE ALL SECTIONS ON THIS PAGE AND SUBMIT AS A PART OF THE APPLICATION FOR A PERMIT UNDER CHAPTER 499, F.S.

A. DO YOU UNDERSTAND THAT A REPACKAGER OF PRESCRIPTION DRUGS IS NOT CONSIDERED A MANUFACTURER FOR THE PURPOSE OF THIS PERMIT AND THAT AN OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER PERMIT IS REQUIRED TO WHOLESALE REPACKAGED DRUGS INTO FLORIDA? ✓ YES ___ NO DO YOU REPACKAGE PRESCRIPTION DRUGS? ___ YES ✓ NO

B. DO YOU UNDERSTAND THAT THIS PERMIT ONLY AUTHORIZES THE DISTRIBUTION OF PRESCRIPTION DRUGS MADE BY YOU, OR YOUR CLIENT, AND THAT IF YOU SELL AND/OR DISTRIBUTE A PRESCRIPTION DRUG MADE BY ANOTHER, YOU WILL BE REQUIRED TO OBTAIN AN ADDITIONAL PERMIT AS AN OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER? ✓ YES ___ NO

C. ANSWER THE FOLLOWING QUESTIONS THAT APPLY TO YOU:

1. YOU ARE RECOGNIZED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) AS THE MANUFACTURER OF A PRESCRIPTION DRUG BECAUSE:
   ___ YOU ARE THE NDA/ANDA/NADA HOLDER FOR A PRESCRIPTION DRUG N/A - Not a manufacturer
   ___ YOU ARE CONSIDERED THE MANUFACTURER OF A DESI PRESCRIPTION DRUG OR OTHER "GRANDFATHERED DRUG"
   ___ YOU ARE THE IMPORTER OF RECORD FOR AN FDA APPROVED PRESCRIPTION DRUG
2. TYPE OF OPERATION ___ OWN LABEL MANUFACTURER ___ CONTRACT MANUFACTURER ✓ Private Label Distributor
   DO YOU COMPLY WITH ALL FEDERAL AND STATE "CURRENT GOOD MANUFACTURING PRACTICES?" ✓ YES ___ NO

D. DOES THE LOCATION FOR WHICH YOU ARE APPLYING SELL PRESCRIPTION DRUGS INTO FLORIDA? ✓ YES ___ NO If no, provide the name(s) and address(es) from which the drugs are sold into Florida. _____

If no, are the companies identified above the drug manufacturer(s) for whom you distribute? ___ YES ___ NO

E. DOES THE LOCATION FOR WHICH YOU ARE APPLYING SHIP PRESCRIPTION DRUGS INTO FLORIDA? ___ YES ✓ NO If no, provide the name(s) and address(es) of all locations that ship prescription drugs into Florida on your behalf. Use an attached sheet if necessary.

Specialty Pharmaceutical Services
15 Ingram Blvd, Ste 100, La Vergne, TN 37086

F. DOES YOUR COMPANY SELL AND/OR DISTRIBUTE ONLY FDA APPROVED DRUGS? ✓ YES ___ NO
If no, explain (for example the products are grandfathered in under the Federal Drug & Cosmetic Act.)

G. WHAT TYPES OF DRUGS DO YOU MANUFACTURE/PHYSICALLY DISTRIBUTE? ✓ Solid Dose ___ Injectables ___ Veterinary ___ Ophthalmic ___ Liquids (oral) ___ Topical ___ Dental ___ Bulk Chemicals

H. IF YOU ARE NOT LOCATED IN THE UNITED STATES, HAVE YOU ATTACHED A LIST IDENTIFYING EACH PRESCRIPTION DRUG YOU INTEND TO IMPORT INTO FLORIDA, AND DOCUMENTATION FROM THE UNITED STATES FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) GIVING YOU APPROVAL TO DO SO? ___ YES ___ NO ✓ NOT APPLICABLE

I. DO YOU INTEND TO MANUFACTURE OR DISTRIBUTE PRESCRIPTION DRUG SAMPLES? ___ YES ✓ NO If yes, you must also obtain a Complimentary Drug Distributor permit (See Rule 64F-12.015(8)(a), F.A.C., for the application requirements).

J. PROVIDE US WITH A PHOTOCOPY OF YOUR LICENSE/PERMIT ISSUED BY YOUR RESIDENT STATE THAT AUTHORIZES THE SALE AND/OR DISTRIBUTION OF PRESCRIPTION DRUGS FROM THE APPLICANT ADDRESS. IF ONE IS NOT NEEDED YOU MUST COMPLY WITH RULE 64F-12.015(7)(e)6., F.A.C.

K. IS THE APPLICANT LICENSED IN ANY OTHER STATE AS A MANUFACTURER OR WHOLESALER OF PRESCRIPTION DRUGS? ✓ YES ___ NO
If yes, provide a listing of all states where licensed, including the license numbers and expiration dates.

L. HAVE YOU REVIEWED s. 499.0121(6)(d)4 & 5, FLORIDA STATUTES, AND UNDERSTAND THE REQUIREMENT TO FILE WITH THE DEPARTMENT, AND UPDATE, A LISTING OF ALL OF YOUR AUTHORIZED DISTRIBUTORS OF RECORD? ✓ YES ___ NO

05/11/10
DATE

SIGNATURE OF OWNER OR CORPORATE OFFICER

USE THIS WORKSHEET FOR CALCULATING THE APPLICATION FEE

Below you will find the permit(s) for which you are applying along with the associated application fee(s). Fill in the appropriate box(es) under "Amount" then add the boxes to calculate your "Total Due." Make checks payable to the **Drugs, Devices & Cosmetics Trust Fund** and mail to: **P.O.Box 6320, Tallahassee, FL 32314-6320**

***If applying for multiple MANUFACTURING permits, you are only required to pay for the one with the highest fee.**
In addition, all manufacturers, **except** Device Manufacturers and Non-Resident Prescription Drug Manufacturers, are required to register their products with the department prior to sale.

PERMIT TYPE	APPLICATION FEE	AMOUNT
If applying for the following permits located IN THE STATE OF FLORIDA an inspection is required; please remit the application fee and inspection fee.		
Prescription Drug Manufacturer	$1,500.00 *	
Prescription Drug Repackager	$1,500.00 *	
Device Manufacturer	$1,200.00 *	
Cosmetic Manufacturer	$1,200.00 *	
Compressed Medical Gas Manufacturer	$1,000.00 *	
Over-the-Counter Drug Manufacturer	$800.00 *	
Product Registration	$30.00 X ___ (number of products) =	
Limited Prescription Drug Veterinary Wholesale Distributor	$1,000.00	
Veterinary Prescription Drug Wholesale Distributor	$1,000.00	
Compressed Medical Gas Wholesale Distributor	$600.00	
Restricted Prescription Drug Distributor - Health Care Entity	$600.00	
Restricted Prescription Drug Distributor - Reverse Distributor	$600.00	
Restricted Prescription Drug Distributor - Destruction	$600.00	
Complimentary Drug Distributor	$500.00	
Veterinary Prescription Drug Retail Establishment	$600.00	
Medical Oxygen Retail Establishment	$600.00	
Freight Forwarder	$600.00	
Third Party Logistics Provider	$600.00	
Retail Pharmacy Drug Wholesale Distributor	$100.00	
	INSPECTION FEE	**$150.00**
	Total Due	
If applying for the following permits located IN THE STATE OF FLORIDA an inspection is not required; please remit ONLY the application fee.		
Restricted Prescription Drug Distributor - Charitable Organization	$600.00	
Restricted Prescription Drug Distributor - Government Programs	$600.00	
Restricted Prescription Drug Distributor - Institutional Research	$600.00	
If applying for the following permits located OUTSIDE THE STATE OF FLORIDA an inspection is not required; please remit ONLY the application fee.		
Limited Prescription Drug Veterinary Wholesale Distributor	$1,000.00	
Veterinary Prescription Drug Wholesale Distributor	$1,000.00	
Complimentary Drug Distributor	$500.00	
Non-resident Prescription Drug Manufacturer	$1,000.00 *	$1,000.00
Third Party Logistics Provider	$600.00	
	Total Due	$1,000.00

DH 1033, Effective July 08

NON-RESIDENT PRESCRIPTION DRUG MANUFACTURER APPLICATION

ACTAVIS KADIAN LLC

RESPONSE TO QUESTION NO. 20:

IDENTIFY BY NAME & ADDRESS EACH PERSON WHO WILL PARTICIPATE IN ADMINISTERING OR OPERATING THE EXSTABLISHMENT

Douglas S. Boothe, President & CEO
3 Walton Way
Chester, NJ 07930

Brenda Vesey, Vice President
18 West Shore Road
Bloomingdale, NJ 07403

John W. LaRocca, Vice President & Secretary
167 Watchung Avenue
Upper Montclair, NJ 07043

Stephen Gallagher, Vice President & Treasurer
31 Claremont Drive
Maplewood, NJ 07040

Christopher C. Young, Vice President, US Operations
29 Stag Place
Lincroft, NJ 07738

NON-RESIDENT PRESCRIPTION DRUG MANUFACTURER APPLICATION

ACTAVIS KADIAN LLC

RESPONSE TO QUESTION NO. 21:

SECTION D LIMITED LIABILITY COMPANY

THE LLC MEMBERS HAVE 0% OWNERSHIP OF THE COMPANY

Douglas S. Boothe, President & CEO
3 Walton Way
Chester, NJ 07930

Brenda Vesey, Vice President
18 West Shore Road
Bloomingdale, NJ 07403

John W. LaRocca, Vice President & Secretary
167 Watchung Avenue
Upper Montclair, NJ 07043

Stephen Gallagher, Vice President & Treasurer
31 Claremont Drive
Maplewood, NJ 07040

AUTHORIZED MEMBER
Terri Nataline, Vice President, Regulatory & Medical Affairs
26 Greaves Place
Cranford, NJ 07016

RESIDENT AGENT
United Corporate Services, Inc.
9200 South Dadeland Blvd., Suite 508
Miami, FL 33156
Tel.: (800) 899-8648

STATE OF FORMATION
Delaware

ACTAVIS KADIAN LLC
STATE AND FEDERAL CORPORATE REGISTRATIONS

STATE/AGENCY	BUSINESS ACTIVITY	TYPE OF LICENSE	PERMIT NO.	EXPIRATION DATE
Alabama	Rx DRUGS & CDS	MFG/WHSE/DIST	**193945**	12/31/2010
	CDS	MFG/WHSE/DIST	**193945**	12/31/2010
Arkansas	Rx DRUGS & CDS	WHSE	**WD03785**	12/31/2010
Iowa	Rx DRUGS & CDS	WHSE	**6990**	12/31/2010
New Jersey	Rx DRUGS	WHSE	**5003872**	1/31/2011
South Dakota	Rx DRUGS	WHSED RUG DIST	**600-1710**	12/31/2010

NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

0699458 COPY

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

60 COLUMBIA RD - BLDG B MORRISTOWN, NJ 07960-

Reg. No.
5003872

ACTAVIS INC
ACTAVIS KADIAN LLC
60 COLUMBIA RD - BLDG B
MORRISTOWN, NJ 07960-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2011

Establishment Copy

ACTAVIS ELIZABETH LLC

ACCOUNT NUMBER	INVOICE NUMBER RETURNS - CR.	DATE MO.	DAY	YEAR	INVOICE AMOUNT	DISCOUNT	NET AMOUNT
	REF040510	04	05	10	1000.00	0.00	1000.00
					1000.00	0.00	1000.00

- DETACH BEFORE DEPOSITING -

THIS CHECK IS VOID WITHOUT A BLUE AND GREEN BACKGROUND AND AN ARTIFICIAL WATERMARK ON THE BACK - HOLD AT AN ANGLE TO VIEW

ACTAVIS ELIZABETH LLC
200 ELMORA AVENUE
ELIZABETH, NEW JERSEY 07207

62-22/311
WACHOVIA BANK OF DELAWARE
BankAddress

NO. 282483

CHECK NUMBER	MO.	DAY	YEAR
282483	04	08	10

One Thousand And No/100 Dollars

$*******1,000.00

PAY TO THE ORDER OF: DRUGS, DEVICES & COSMETICS
PO BOX 6320
TALLAHASSEE FL 32314

AUTHORIZED SIGNATURE

AUTHORIZED SIGNATURE

BORDER CONTAINS MICROPRINTING

⑈282483⑈ ⑆031100225⑆ 2079951076361⑈

Silvia Sanles

From: Silvia Sanles
Sent: Thursday, April 08, 2010 9:45 AM
To: 'trisha_shannon@doh.state.fl.us'
Subject: Private Label License Requirements-FL
Importance: High

Hi Trisha,

Per our conversation earlier today, below is a description of our private label facilities. Please advise if a non-resident Florida license would be the proper license to obtain for both companies.

Actavis Kadian LLC is a Private Label Distributor who does not own the ANDA/drug product. The product is manufactured by a Florida licensed facility, and is distributed by a 3rd party logistics provider (licensed in Florida). Actavis Kadian LLC never handles the physical drug product; it is sold under the Actavis Kadian LLC labeler code.

Actavis Inc. is a Private Label Distributor who does own the ANDA (s)/drug product. The product is manufactured by a Florida licensed facility, and distributed by a 3rd party logistics provider (licensed in Florida). Actavis Inc. never handles the physical drug product; the product is sold under the Actavis Inc. labeler code.

Please be aware, that both companies are located at the same facility, 60 Columbia Rd, Bldg B, Morristown, NJ 07960.

Regards,

Silvia Sanles
Supervisor, Regulatory Affairs

actavis
creating value in pharmaceuticals

Actavis
60 Columbia Rd. Bldg B *t* +1 973-889-6960 @ SSanles@actavis.com
Morristown , NJ 07960 United States *w* www.actavis.com
Internal VoIP number *t* 1256960

ACTAVIS INC. CHECK REQUEST

Checks to be issued on Friday

Make Check Payable to:	
Name	Drugs, Devices & Cosmetics Trust Fund
Address	PO Box 6320
City	Tallahassee
State, Zip	FL, 32314
Phone	850-245-4292

Amount -$	1000.00
Dept. and Cacti or Capex No.	98-35575-705

Reason Explain in Detail	Florida Initial Rx Drugs & CDS application for Actavis Kadian LLC
SPECIAL HANDLING INSTRUCTIONS	Please return to Silvia Sanles/Morristown

Originated By:	SILVIA SANLES
	Signature:
	Date: 3/15/10 Ext.: 1256960

Approved By:	TERRI NATALINE
	Signature:
	Date: 4/05/10 Ext.: 1202317

Approved By:	
Finance Review	Signature:
	Date: Ext.
Please attach all supporting documents. Invoices, Quotes, Proof of Delivery, etc.	

USE THIS WORKSHEET FOR CALCULATING THE APPLICATION FEE

Below you will find the permit(s) for which you are applying along with the associated application fee(s). Fill in the appropriate box(es) under "Amount" then add the boxes to calculate your "Total Due." Make checks payable to the **Drugs, Devices & Cosmetics Trust Fund** and mail to: **P.O.Box 6320, Tallahassee, FL 32314-6320**

***If applying for multiple MANUFACTURING permits, you are only required to pay for the one with the highest fee.**
In addition, all manufacturers, **except** Device Manufacturers and Non-Resident Prescription Drug Manufacturers, are required to register their products with the department prior to sale.

PERMIT TYPE	APPLICATION FEE	AMOUNT
If applying for the following permits located **IN THE STATE OF FLORIDA an inspection is required**; please remit the application fee and inspection fee.		
Prescription Drug Manufacturer	$1,500.00 *	_____
Prescription Drug Repackager	$1,500.00 *	_____
Device Manufacturer	$1,200.00 *	_____
Cosmetic Manufacturer	$1,200.00 *	_____
Compressed Medical Gas Manufacturer	$1,000.00 *	_____
Over-the-Counter Drug Manufacturer	$800.00 *	_____
Product Registration	$30.00 X ___ (number of products) =	_____
Limited Prescription Drug Veterinary Wholesale Distributor	$1,000.00	_____
Veterinary Prescription Drug Wholesale Distributor	$1,000.00	_____
Compressed Medical Gas Wholesale Distributor	$600.00	_____
Restricted Prescription Drug Distributor - Health Care Entity	$600.00	_____
Restricted Prescription Drug Distributor - Reverse Distributor	$600.00	_____
Restricted Prescription Drug Distributor - Destruction	$600.00	_____
Complimentary Drug Distributor	$500.00	_____
Veterinary Prescription Drug Retail Establishment	$600.00	_____
Medical Oxygen Retail Establishment	$600.00	_____
Freight Forwarder	$600.00	_____
Third Party Logistics Provider	$600.00	
Retail Pharmacy Drug Wholesale Distributor	$100.00	_____
	INSPECTION FEE	**$150.00**
	Total Due	_____
If applying for the following permits located **IN THE STATE OF FLORIDA an inspection is not required**; please remit **ONLY** the application fee.		
Restricted Prescription Drug Distributor - Charitable Organization	$600.00	_____
Restricted Prescription Drug Distributor - Government Programs	$600.00	_____
Restricted Prescription Drug Distributor - Institutional Research	$600.00	_____
If applying for the following permits located **OUTSIDE THE STATE OF FLORIDA an inspection is not required**; please remit **ONLY** the application fee.		
Limited Prescription Drug Veterinary Wholesale Distributor	$1,000.00	_____
Veterinary Prescription Drug Wholesale Distributor	$1,000.00	_____
Complimentary Drug Distributor	$500.00	_____
Non-resident Prescription Drug Manufacturer	$1,000.00 *	$1,000.00
Third Party Logistics Provider	$600.00	_____
	Total Due	$1,000.00

DH 1033, Effective July 08