U. S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
IMPORTER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Firm name : Actavis Laboratories FL, Inc. Importer Registration Number – RW0439047

Dear DEA Registrant:

In order to process your company's request to import Schedule I and/or II controlled substances, the DEA's Regulatory Unit (ODGR) must obtain the information requested in this questionnaire.

Product - Fentanyl

THIS QUESTIONNAIRE IS BEING SUBMITTED BY THE FOLLOWING:

SIGNATURE OF PERSON: _____
(PLEASE SIGN)

NAME OF PERSON SUBMITTING: Thomas P. Napoli
(PLEASE PRINT)

TITLE OF PERSON: Associate Director, Controlled Substance Compliance

NAME OF COMPANY: Actavis Laboratories FL, Inc.

DEA REGISTRATION# RW0439047

TELEPHONE# 862-261-7193

E-MAIL ADDRESS: tom.napoli@actavis.com

FAX NUMBER: 862-261-7927

DATE OF SUBMISSION: November 18, 2014

The following questions pertain to your request to import Schedule I and/or II controlled substances. Please provide a detailed response to the following questions for each Schedule I and/or II drug code your company wishes to import.

1. What type of controlled substance does your company intend to import: bulk or dosage form?

   Dosage Form

PLAINTIFFS TRIAL EXHIBIT
P-04813_00001

Actavis Laboratories FL, Inc.– Fentanyl continued

7. **Who are your current and prospective customers? Please provide a list of names, addresses, and DEA numbers for each controlled substance. Please attach copies of letters of interest from these customers.**

   Actavis Laboratories FL, Inc. (Analytical testing)
   2945 West Corp. Lakes Blvd
   Weston, Florida 33331
   DEA# RA0135499

   Due to the early stages in this process we are unable to determine which facilities would be most suitable for the trials. All sites under consideration will be DEA registered facilities. We will notify you once a decision has been confirmed.

   Also our primary company that will perform the clinical portion will be WTI or Watson Therapeutics, Inc. (RC0452742) 3400 Enterprise Way, Miramar, FL 33025

8. **Will the controlled substance(s) you propose to import be used to manufacture controlled substances? If so, how, and in what quantity, are they to be manufactured?**

   No, the brand product will only be used for analysis.

9. **Does your company have previous experience handling controlled substances? Please explain.**
   Yes, Actavis (and its subsidiaries), currently maintains 52 DEA registrations (Manufacturer, Analytical Lab, Researcher, Export, Distributor and Import) at 21 different sites across the US. Attached is a copy of Watson/Actavis' current registration list.

10. **Does your company have previous experience in the importation of controlled substances? Please explain.**

    Yes, Actavis currently has seven active importer registrations with DEA, Corona, CA (RW0439047), SLC,UT (RW02589881), Gurnee, IL (RW0387262), Davie, FL (RW0439047), Sunrise, FL (RW0452033), Edison, NJ (RA0431700) and Elizabeth, NJ (RK0147199).

11. **When does your company anticipate selling a commercial product?**

    Our plan is to commercially export this product for sale in 2017.

THE INFORMATION IN THIS QUESTIONAIRE IS CURRENT
AS OF THIS DATE 11/18/2014

Actavis Laboratories FL, Inc.– Fentanyl continued

12. **Please provide a written description of what resources your company has committed to the establishment of your importation business pertaining to these drug codes. (For example, does your company intend to make, or has it made, any changes to your physical security, security system, production equipment, or recordkeeping system)? Please provide a proposed time-frame for the completion of these activities.**

    Actavis currently follows all DEA requirements for storing, handling, security, and record keeping procedures for class II products. All CII's are kept in a vault or in an approved safe in the lab monitored by cameras.

13. **Does your company currently possess any other registrations from the Drug Enforcement Administration pertaining to controlled substances? If so, please include the registration number(s), business activity, drug schedules, and expiration date for each registration.**

    See attachment.

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AS OF THIS DATE 11/18/2014

Actavis Laboratories FL, Inc.– Fentanyl continued

SUPPLEMENTAL INFORMATION FOR NEW APPLICANTS OR FOR THE ADDITION OF A SPECIFIC CONTROLLED SUBSTANCE TO AN EXISTING DEA REGISTRATION – IMPORTERS

Importer Questions:

(Note: To assist you in answering questions numbers #s 14 through 16, you may wish to consult the following DEA final order published in the Federal Register: Lyle E. Craker; Denial of Application, 74 FR 2101 (January 14, 2009).

If you are requesting to import a Schedule I or II controlled substance for the first time either as an entirely new applicant for DEA registration or adding a specific controlled substance to an existing DEA registration, you must answer the following questions for each controlled substance:

14. Please describe your company's past experience with controlled substances. Please be specific with regard to dates, types of business activity, and schedules of controlled substances handled.

Yes, Actavis (and its subsidiaries), currently maintains 52 DEA registrations (Manufacturer, Analytical Lab, Researcher, Export, Distributor and Import) at 21 different sites across the US. Attached is a copy of Watson/Actavis' current registration list.

15. If your company is applying to obtain a registration as an importer because it cannot purchase the needed controlled substance from existing bulk manufacturers for its business activity, please provide the names of the existing registered bulk manufacturers you contacted. Please include dates of contact, persons contacted, and method of contact.

Not Applicable. We intend to procure brand for clinical and analytical purposes only.

16. Please describe in detail whether your company's proposal to import controlled substances will promote technical advances in the art of manufacturing these substances and in the development of new substances.

No. Actavis will be engaged in the development of generic products for ex-US markets.

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Actavis Laboratories FL, Inc.– Fentanyl continued

Note: **In answering question #17, your company bears the burden of demonstrating that either the existing supply or competition is inadequate within the meaning of 21 USC § 823 (a)(1). Particular consideration should be given to whether the existing registered bulk manufacturers and importers of the controlled substance for which you seek registration can produce an adequate and uninterrupted supply of this substance under adequately competitive conditions and, if such competition among existing registrants is inadequate, whether such competition will not be rendered adequate by the registration of additional domestic bulk manufacturers. DEA has traditionally focused on the historical and present prices charged to those who lawfully acquire the controlled substance from the existing registered bulk manufacturers. In the past, successful applicants for registration under 21 USC § 823 (a)(1) have focused on prices charged by the existing market for the schedule I or II controlled substance in question and shown those prices to be unreasonable.**

17. **Please identify the following:**

Not Applicable. Actavis is requesting to obtain limited quantities of ex-US brand for development of generics for export.

a. **your competitors, their products, and their prices and explain why the supply or competition is inadequate.**

b. **Why are current prices charged by your competitors to those who lawfully acquire the controlled substance in question unreasonable?**

c. **Please provide evidence showing that current market prices are clearly and persistently excessive.**

d. **Please state your prices and explain why they are more competitive than the current prices in the existing market.**

e. **Provide evidence that you can produce the controlled substance in question at a lower cost than your competitors?**

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Actavis Laboratories FL, Inc.– Fentanyl continued

Responses to this questionnaire may be returned to the DEA's Regulatory Unit (ODGR) by mail, email or by fax:

Regular Mail/Fed Ex/UPS/DHL:

Drug Enforcement Administration
Attn: 303 Processing/Michele Herron/ODGR
8701 Morrissette Drive
Springfield, VA 22152

Facsimile:

Fax# (202) 307-8101
Attn: 303 Processing/Michele Herron/ODGR

If you have any questions, please contact one of the following individuals:

Name	Telephone#	E-Mail Address
Michele Herron, S/C (Staff Coordinator)	(202) 307-4948	Michele.d.Herron@usdoj.gov
Marquita Brown, P/A (Program Analyst)	(202) 353-1199	Marquita.L.Brown@usdoj.gov

THE INFORMATION IN THIS QUESTIONAIRE IS CURRENT
AS OF THIS DATE 11/18/2014

Location	Type of License	Schedules Authorized	Renewal Date	DEA #
Watson Laboratories, Inc. 311 Bonnie Circle (Bldg. 4) Corona, CA 92880	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2015	RW0202197
Watson Laboratories, Inc. 311 Bonnie Circle (Bldg. 4) Corona, CA 92880	Manufacturer	2, 2N, 3, 3N, 4, 5	5/31/2015	RW0331885
Watson Laboratories, Inc. 311 Bonnie Circle (Bldg. 4) Corona, CA 92880	Researcher	2, 2N, 3, 3N, 4, 5	5/31/2015	RW0193639
Watson Laboratories, Inc. 132 A Business Ctr. Dr. (Bldg. 1) Corona, CA 92880	Researcher	2, 2N, 3, 3N, 4, 5	5/31/2015	RW0103161
Watson Laboratories, Inc. 132 A Business Ctr. Dr. (Bldg. 1) Corona, CA 92880	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2015	RW0316756
Watson Laboratories, Inc. 132 A Business Ctr. Dr. (Bldg.1) Corona, CA 92880	Manufacturer	2, 2N, 3, 3N, 4, 5	5/31/2015	RW0117261
Watson Laboratories, Inc. 2455 Wardlow Rd. (Bldg. 5) Corona, CA 92880	Manufacturer	2, 2N, 3, 3N, 4	5/31/2015	RW0288933
Actavis Pharma, Inc. 2455 Wardlow Road (Bldg. 5) Corona, CA 92880	Exporter	2, 2N, 3, 3N, 4, 5	6/30/2015	RW0246050
Actavis Pharma, Inc. 2455 Wardlow Road (Bldg. 5) Corona, CA 92880	Importer	2, 2N, 3N, 4, 5	6/30/2014 (submitted)	RW0322937
Actavis Pharma, Inc. 2455 Wardlow Rd. (Bldg. 5) Corona, CA 92880-2882	Distributor	2, 2N, 3, 3N, 4	6/30/2015	RW0288921
Actavis Pharma, Inc. 605 Tri-State Parkway Gurnee, IL 60031	Exporter	2, 2N, 3, 3N, 4, 5	6/30/2015	RW0271142
Actavis Pharma, Inc. 605 Tri-State Parkway Gurnee, IL 60031	Importer	3N, 4, 5	6/30/2015	RW0387262
Actavis Pharma, Inc. 605 Tri-State Parkway Gurnee, IL 60031	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2015	RW0237900

Location	Type of License	Schedules Authorized	Renewal Date	DEA #
Watson Therapeutics, Inc. 3400 Enterprise Way Miramar, FL 33025	Researcher (II-V)	2, 2N, 3, 3N, 4, 5	6/30/2015	RC0452742
Actavis Pharmaceuticals NJ, Inc. 661 Route 1 South North Brunswick, NJ 08902	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	6/30/2015	RW0438300
Actavis Laboratories UT, Inc. 575/577/579Chipeta Way Salt Lake City, UT 84108	Manufacturer	2, 2N, 3, 3N, L1	6/31/2015	RW0259893
Actavis Laboratories UT, Inc. 575/577/579 Chipeta Way Salt Lake City, UT 84108	Importer	3N	6/31/2015	RW0372300
Actavis Laboratories UT, Inc. 575/577/579 Chipeta Way Salt Lake City, UT 84108	Exporter	2, 2N, 3, 3N	6/31/2015	RW0259881
Actavis Laboratories UT, Inc. 575/577/579 Chipeta Way Salt Lake City, UT 84108	Distributor	2, 2N, 3, 3N, 4, 5	6/31/2015	RW0289959
Actavis Laboratories UT, Inc. 575/577/579 Chipeta Way Salt Lake City, UT 84108	Analytical Lab	2, 2N, 3, 3N, 4, 5	6/31/2015	RW0259514
Actavis Laboratories FL, Inc. 4955 Orange Drive Davie, FL 33314	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2015	RA0270025
Actavis Laboratories FL, Inc. 4955 Orange Drive Davie, FL 33314	Manufacturer	2, 2N, 3, 3N, 4, 5, L1	5/31/2015	RA0279946
Actavis Laboratories FL, Inc. 4955 Orange Drive Davie, FL 33314	Importer	3N, 4, 5	5/31/2015	RW0439047
Actavis Laboratories FL, Inc. 4955 Orange Drive Davie, FL 33314	Exporter	2, 2N, 3, 3N, 4, 5	5/31/2015	RW0439035
Actavis Laboratories FL, Inc. 2945 W. Corp Lks Blvd. Weston, FL 33331	Analytical Lab	1, 2, 2N 3, 3N, 4, 5	5/31/2015	RA0315499
Actavis Laboratories FL, Inc. 2945 W. Corp Lks Blvd. Weston, FL 33331	Manufacturer	2, 2N, 3, 3N,, 4, 5	5/31/2015	RA0297033

Actavis DEA Registrations (Revised 11/18/2014)

Location	Type of License	Schedules Authorized	Renewal Date	DEA #
Actavis Laboratories FL, Inc. 13900 NW 2nd Street Sunrise, FL 33325	Chemical Distributor	List I	6/30/2015	006159ADY
Actavis Laboratories FL, Inc. 13900 NW 2nd Street Sunrise, FL 33325	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	4/30/2015	RA0352651
Actavis Laboratories FL, Inc. 13900 NW 2nd Street Sunrise, FL 33325	Manufacturer	2, 2N, 3, 3N, 4, L1	5/31/2015	RA0352663
Actavis Laboratories FL, Inc. 13900 NW 2nd Street Sunrise, FL 33325	Importer	3N, 4,5	5/31/2015	RW0452033
Actavis Laboratories FL, Inc. 13900 NW 2nd Street Sunrise, FL 33325	Exporter	2, 2N, 3,3N, 4,5	5/31/2015	RW0452045
Anda, Inc. 2915 Weston Road Weston, FL 33331	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2015	RA0180733
Anda Pharmaceuticals, Inc. 6500 Adelaide Court Groveport, OH 43125	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2015	RA0287020
Anda, Puerto Rico, Inc. Pepsi Industrial Park PR#2 KM 19.5 BO. Candelaria Toa Baja, PR 00949	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2015	RA0394748
Anda Pharmaceuticals, Inc. 8644 Polk Lane Olive Branch, MS 38654	Distributor	2, 2N, 3, 3N, 4, 5	Pending	Pending
Actavis LLC 47 Brunswick Avenue Edison, NJ 08817	Distributor	2, 2N, 3, 4, 5	6/30/2015	RA0419540
Actavis LLC 47 Brunswick Avenue Edison, NJ 08817	Manufacturer	2, 2N, 3, 4, 5	6/30/2015	RA0419552
Actavis LLC 47 Brunswick Avenue Edison, NJ 08817	Importer	3, 4	6/30/2015	RA0431700

Location	Type of License	Schedules Authorized	Renewal Date	DEA #
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Manufacturer	2, 2N, 3, 3N, 4, 5	6/30/2015	RK0146806
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2015	RK0146818
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Importer	4, 5	6/30/2015	RK0147199
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Exporter	4, 5	6/30/2015	RK0146832
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Researcher	2, 2N, 3, 3N, 4, 5	6/30/2015	RK0146820
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Analytical lab	1, 2, 2N, 3, 3N, 4, 5	6/30/2015	RP0192637
Actavis Mid Atlantic LLC 10065 Red Run Blvd. Owings Mills, MD 21117	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	6/30/2015	RP0188931
Actavis Mid Atlantic LLC 10065 Red Run Blvd. Owings Mills, MD 21117	Manufacturer	2, 3, 3N, 4, 5, L1	6/30/2015	RA0395675
Warner Chilcott Company, LLC Carr.2, KM. 45.7, BO. Cotto Norte Manati, PR 00674	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2015	RW0463389
Warner Chilcott Company, LLC Carr.2, KM. 45.7, BO. Cotto Norte Manati, PR 00674	Manufacturer	2, 3	5/31/2015	RW0456865
Forest Pharmaceuticals Subsidiary of Forest Laboratories, Inc. 13600 Shoreline Dr. St. Louis, MO 63045	Distributor	2, 3, 3N, 4, 5	12/31/2014	PO0237594
Forest Research Institute, Inc. 155 Commerce Drive Hauppauge, NY 11788	Distributor	3, 3N, 4, 5	9/30/2015	RF0384634

Actavis DEA Registrations (Revised 11/18/2014)

Location	Type of License	Schedules Authorized	Renewal Date	DEA #
Forest Research Institute, Inc. 49 Mall Drive Commack, NY 11725	Manufacturer	2, 3, 3N, 4, 5	9/30/2015	RF0314029
Forest Research Institute, Inc. 49 Mall Drive Commack, NY 11725	Analytical Lab	2, 3, 3N, 4, 5	9/30/2015	RF0314043
Inwood Laboratories 220 Sea Lane Farmingdale, NY 11735	Analytical Lab	2, 2N, 3, 3N, 4, 5	11/30/2014	RI0218190