

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

Firms name : Watson Pharma, Inc. Importer Registration Number – RW0322937

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 - Hydromorphone

THIS QUESTIONNAIRE IS BEING SUBMITTED BY THE FOLLOWING:

SIGNATURE OF PERSON: _____
(PLEASE SIGN)

Thomas P. Napoli

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

TITLE OF PERSON: Associated Director DEA Affairs

NAME OF COMPANY: Watson Pharma, Inc.

DEA REGISTRATION# RW0322937

TELEPHONE# 862-261-7193

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

FAX NUMBER: 862-261-7927

DATE OF SUBMISSION: 5/3/2013

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-04814_00001

Watson Pharma, Inc. – Hydromorphone continued

2. **What is the purpose for the importation of the controlled substance? (For example: narcotic raw material for bulk manufacture, clinical trials, research, analytical purposes, or distribution).**

Clinical trials, research & analytical purposes

3. **Why is a foreign source of supply being used instead of a domestic source?**

The intent is to market Watson finished product in ex-US markets. Clinical trials are required against the brand product from the target market.

4. **What is the name, address, method of shipment, and method of delivery for each supplier of the controlled substance your company proposes to import?**

The supplier is from Canada, our sister company. (Cobalt Pharmaceuticals, 6500 Kitimat Road, Mississauga, Ontario L5N2B8 Canada)

Method of shipment – Air

Method of delivery – FedEx or DHL

5. **Does your company have a firm commitment from the supplier(s) of each substance proposed for importation? Yes**

- a. **What is the time period of the commitment?**

Upon receipt of permits (1-2 months)

- b. **What quantity is involved?**

1,000 – 2,000 units of each strength

(Please attach copies of all commitment letters)

6. **What quantity of each controlled substance does your company anticipate importing on an annual basis?**

1,000 – 2,000 units of each strength

Firms name & DEA #:
Watson Pharma, Inc.

- 3 -

Watson Pharma, Inc. – Hydromorphone 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.**

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

Clinical trial facilities

Worldwide Clinical Trials
2455 NE Loop 410 Suite 150
San Antonio, TX 78217
DEA# RC0328701

- 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, Watson Laboratories /Watson Pharma currently maintains 26 DEA registrations (Manufacturer, Analytical Lab, Researcher, Export, Distributor and Import) at 9 different sites across the US. Attached is a copy of Watson's current registration list.

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

Yes, Watson currently has three active importer registrations with DEA, Corona, CA (RW0322937), SLC (RW02589881) and IL (RW0387262).

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

Our plan is to commercially export this product for sale in 2014.

THE INFORMATION IN THIS QUESTIONNAIRE IS CURRENT
AS OF THIS DATE 4/25/2013

Firms name & DEA #:
Watson Pharma, Inc. RW0322937

- 4 -

Watson Pharma, Inc. – Hydromorphone 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.

Watson 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.

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 Morrisette 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:

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

Firms name & DEA #:
Watson Pharma, Inc.

- 5 -

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Watson DEA Registrations (Revised 5/3/2013)

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	5/31/2013	RW0202197
Watson Laboratories, Inc. 311 Bonnie Circle (Bldg. 4) Corona, CA 92880	Manufacturer	2, 2N, 3, 3N, 4, 5	5/31/2013	RW0331885
Watson Laboratories, Inc. 311 Bonnie Circle (Bldg. 4) Corona, CA 92880	Researcher	2, 2N, 3, 3N, 4, 5	5/31/2013	RW0193639
Watson Laboratories, Inc. 132 A Business Ctr. Dr. (Bldg. 1) Corona, CA 92880	Researcher	2, 2N, 3, 3N, 4, 5	5/31/2013	RW0103161
Watson Laboratories, Inc. 132 A Business Ctr. Dr. (Bldg. 1) Corona, CA 92880	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2013	RW0316756
Watson Laboratories, Inc. 132 A Business Ctr. Dr. (Bldg. 1) Corona, CA 92880	Manufacturer	2, 2N, 3, 3N, 4, 5	5/31/2013	RW0117261
Watson Laboratories, Inc. 2455 Wardlow Rd. (Bldg. 5) Corona, CA 92880	Manufacturer	2, 2N, 3, 3N, 4	5/31/2013	RW0288933
Watson Pharma, Inc. 2455 Wardlow Road (Bldg. 5) Corona, CA 92880	Exporter	2, 2N, 3, 3N, 4, 5	5/31/2013	RW0246050
Watson Pharma, Inc. 2455 Wardlow Road (Bldg. 5) Corona, CA 92880	Importer	2, 2N, 3N, 4, 5	5/31/2013	RW0322937
Watson Pharma, Inc. 2455 Wardlow Rd. (Bldg. 5) Corona, CA 92880-2882	Distributor	2, 2N, 3, 3N, 4	5/31/2014	RW0288921
Watson Pharma, Inc. 605 Tri-State Parkway Gurnee, IL 60031	Exporter	2, 2N, 3, 3N, 4, 5	5/31/2014	RW0271142
Watson Pharma, Inc. 605 Tri-State Parkway Gurnee, IL 60031	Importer	3N, 4, 5	5/31/2014	RW0387262
Watson Pharma, Inc. 605 Tri-State Parkway Gurnee, IL 60031	Distributor	2, 2N, 3, 3N, 4, 5	5/31/2014	RW0237900

Watson DEA Registrations (Revised 5/3/2013)

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Watson Laboratories, Inc. 700 East Business Center Drive Mount Prospect, IL 60056	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2014	RW0322785
Watson Pharmaceuticals, Inc. 661 Route 1 South North Brunswick, NJ 08902	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2014	RW0438300
Watson Laboratories Inc, Utah 575/577/579 Chipeta Way Salt Lake City, UT 84108	Manufacturer	2, 2N, 3, 3N	5/31/2014	RW0259893
Watson Laboratories Inc. Utah 575/577/579 Chipeta Way Salt Lake City, UT 84108	Importer	3N	5/31/2014	RW0372300
Watson Laboratories Inc. Utah 575/577/579 Chipeta Way Salt Lake City, UT 84108	Exporter	2, 2N, 3, 3N	5/31/2014	RW0259881
Watson Laboratories Inc. Utah 575/577/579 Chipeta Way Salt Lake City, UT 84108	Distributor	2, 2N, 3, 3N, 4, 5	5/31/2014	RW0289959
Watson Laboratories Inc, Utah 575/577/579 Chipeta Way Salt Lake City, UT 84108	Analytical Lab	2, 2N, 3, 3N, 4, 5	5/31/2014	RW0259514
Watson Laboratories, Inc. - Florida 4955 Orange Drive Ft. Lauderdale, FL 33314	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2013	RA0270025
Watson Laboratories, Inc. - Florida 4955 Orange Drive Ft. Lauderdale, FL 33314	Manufacturer	2, 2N, 3, 4, 5, L1	5/31/2013	RA0279946
Watson Laboratories, Inc. - Florida 4955 Orange Drive Ft. Lauderdale, FL 33314	Importer	5	5/31/2013	RW0439047
Watson Laboratories, Inc. - Florida 4955 Orange Drive Ft. Lauderdale, FL 33314	Exporter	2, 2N, 3, 4, 5	5/13/2013	RW0439035
Watson Laboratories, Inc. - Florida 2945 W. Corp Lks Blvd. Weston, FL 33331	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	5/31/2013	RA0315499
Watson Laboratories, Inc. - Florida 2945 W. Corp Lks Blvd. Weston, FL 33331	Manufacturer	2, 2N, 3, 4, 5	5/31/2013	RA0297033

Watson DEA Registrations (Revised 5/3/2013)

Location	Type of License	Schedules Authorized	Renewal Date	DEA #
Watson Laboratories, Inc. - Florida 13900 NW 2 nd Street Sunrise, FL 33325	Chemical Distributor	List I	5/31/2013	006159ADY
Watson Laboratories, Inc. - Florida 13900 NW 2 nd Street Sunrise, FL 33325	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	4/30/2014	RA0352651
Watson Laboratories, Inc. - Florida 13900 NW 2 nd Street Sunrise, FL 33325	Manufacturer	2, 2N, 3, 4, L1	5/31/2013	RA0352663
Watson Laboratories, Inc. - Florida 13900 NW 2 nd Street Sunrise, FL 33325	Importer	4,5	Pending	Pending
Watson Laboratories, Inc. - Florida 13900 NW 2 nd Street Sunrise, FL 33325	Exporter	2, 2N, 3, 4,5	Pending	Pending
Anda, Inc. 2915 Weston Road Weston, FL 33331	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2014	RA0180733
Anda Pharmaceuticals, Inc. 6500 Adelaide Court Groveport, OH 43125	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2014	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	6/30/2013	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	6/30/2013	RA0419540
Actavis LLC 47 Brunswick Avenue Edison, NJ 08817	Manufacturer	2, 2N, 3, 4, 5	6/30/2013	RA0419552
Actavis LLC 47 Brunswick Avenue Edison, NJ 08817	Importer	3, 4	6/30/2013	RA0431700

Watson DEA Registrations (Revised 5/3/2013)

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	6/30/2013	RK0146806
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Distributor	2, 2N, 3, 3N, 4, 5	6/30/2013	RK0146818
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Importer	4, 5	6/30/2013	RK0147199
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Exporter	4, 5	6/30/2013	RK0146832
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Researcher	2, 2N, 3, 3N, 4, 5	6/30/2013	RK0146820
Actavis Elizabeth LLC 200 Elmora Avenue Elizabeth, NJ 07207	Analytical lab	1, 2, 2N, 3, 3N, 4, 5	6/30/2013	RP0192637
Actavis Mid Atlantic LLC 1877 Kawai Road Lincolnton, NC 28092	Manufacturer	2, 3, 4, 5, L1	6/30/2013	RB0185579
Actavis Mid Atlantic LLC 1877 Kawai Road Lincolnton, NC 28092	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	6/30/2013	RB0185581
Actavis Mid Atlantic LLC 10065 Red Run Blvd. Owings Mills, MD 21117	Analytical Lab	1, 2, 2N, 3, 3N, 4, 5	6/30/2013	RP0188931
Actavis Mid Atlantic LLC 10065 Red Run Blvd. Owings Mills, MD 21117	Manufacturer	2, 3, 3N, 4, 5, L1	6/30/2013	RA0395675
Actavis South Atlantic LLC 13800 N.W. 2 nd Street, Ste. 190 Sunrise, FL 33325	Manufacturer	2, 2N, 3, 3N, 4, 5	6/30/2013	RA0321062
Actavis South Atlantic LLC 13800 N.W. 2 nd Street, Ste. 190 Sunrise, FL 33325	Analytical Lab	2, 2N, 3, 3N, 4, 5	6/30/2013	RA0311112