DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

Mr. Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia 22202

Dear Mr. Rannazzisi:

This is the response to your letter dated February 25, 2010 to the Food and Drug Administration, Center for Drug Evaluation and Research (FDA/CDER), requesting estimates of medical, scientific and reserve stock needs for calendar years 2009 and 2010 for Schedule I and II substances, pursuant to 21 CFR Part 1303 (21 United States Code [U.S.C.] 826 and 42 U.S.C., Section 242). The Controlled Substance Staff in the Office of the Center Director, FDA/CDER, has been requested to respond.

We provide forecasts on the usage of thirty-two Schedule II substances for the years 2010, 2011 and 2012. More variability in some of the forecasts may be the result of ongoing activities by the Federal Government to improve the use of Schedule II products by patients and prescribers.

Forecasting Methodology

Monthly purchased data, which are the total of retail and non-retail sales for thirty-two substances, are extracted from the IMS Health, National Sales Perspectives™ database. The IMS Health, National Sales Perspectives™ measures the volume of drug products and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets. The retail market includes the following pharmacy settings: chain drug stores, independent pharmacies, mass merchandisers, grocery stores and mail order pharmacies. The non-retail market includes clinics, federal and non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care and other miscellaneous settings.

The accuracy of the usage data provided depends on many different factors, including both sampling and non-sampling errors. The IMS Health, National Sales Perspectives™ does not provide a direct estimate of use but does provide a national estimate of units (in kilograms) sold from the manufacturer to various channels of distribution. The quantities of products purchased by retail and non-retail channels of distribution may be a possible surrogate for use, assuming that facilities purchase drugs in quantities reflective of actual consumer use.

The forecasting method relies on a mathematical model and can be accurate only to the extent that the environment of the drug use system remains essentially the same as in past years. Accuracy of the forecast is affected by unexpected changes in consumption, supply, data collection or IMS Health's drug categorization and sampling plan. The mathematical modeling process involves only

objective factors. If deterministic factors not specified in advance are operative, reliability of the forecasted values is decreased. Predictions of usage change for 2010, 2011 and 2012 should be carefully interpreted because the precision of the forecast reduces with time into the future.

Each year, IMS Health adjusts the complete database by applying correction factors to update product usage data. Such factors may include a "re-calibration" of reported values or shifts in series reflecting new use of a drug containing the substance of interest. Such changes can result in the forecast estimate for a given year that differs from the estimate given in previous years. Fortunately, the correction factors for most substances are small.

II. Tabular Data

The *observed* usage (purchases in kilograms) of Schedule II substances in 2008 and 2009 and the percent changes based on the *observed* values of the current year and the previous year were provided by CDER's Division of Biometrics and are presented in **Table 1.**

Predicted usages (purchases in kilograms) of the Schedule II substances for 2010, 2011 and 2012 are also provided in **Table 1.** Each predicted value is an estimate subject to variation.

The *observed* and *predicted* usages for 2009 (that were forecasted in 2008) are consistent, in general, for all the drugs and substances with the exception of the values for remifentanil and sufentanil. This may be the result of methodological and statistical issues that relate to the small quantities of sales of each drug substance and large percent changes in sales quantities over the past decade.

Other substances also noted in the previous reports with similarly extreme values were amobarbital, diphenoxylate, meperidine, difenoxin and propoxyphene. Most of these extreme values occurred before 1991 and hence it should not be an influential factor in the current assessment.

For ephedrine and pseudoephedrine purchase and usage, data were available from February 2002 to December 2009. For these two substances forecasting usage is provided for 2009 and 2010 only, because the forecasts were not reliable for later years due to the limitations of available usage data. Schedule IV substances pentazocine, temazepam and zolpidem forecasting usage is provided for 2009 and 2010 only.

We are not providing forecast usage for the following Schedule I and II substances: etorphine, gamma-hydroxybutyric acid (GHB), LAAM, lisdexamfetamine, marijuana, noroxymorphone, phenylpropanolamine, propiram, psilocybin, tapentadol and thebaine because data regarding the usage of these substances were not available. Schedule IV substances difenoxin,[1] halazepam, mazindol and prazepam are also not included in this analysis due to lack of data.

We are providing current information on new drug products and abbreviated new drug applications for drug products containing Schedule II drugs approved between January 2009 and March 2010 in **Table 2** and **Table 3.**

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1 Schedule IV difenoxin product is described in 21 CFR 1308.14 as follows: Containing not more than 1 mg difenoxin and not less than 25 µgm atropine sulfate per dosage form.

In Table 4 we have listed products which were discontinued during 2009.

- Comments on *Observed* usages in 2009 (See Table 1).

There was an increase in the *observed* use of each of the following substances in 2009 compared to 2008: alfentanil (6.9 percent), amobarbital (108.0 percent), amphetamine (16.8 percent), buprenorphine (38.5 percent), dronabinol (6.7 percent), hydrocodone (9.0 percent), hydromorphone (17.2 percent), methadone (2.5 percent), methylphenidate (2.2 percent), morphine (8.0 percent), oxycodone (11.7 percent), oxymorphone (37.5 percent), remifentanil (3.3 percent), secobarbital (15.5 percent), temazepam (2.4 percent) and zolpidem (13.6 percent).

The increase in the *observed* usage for the following substances continued in 2009 and is *predicted* for 2010: methylphenidate, morphine, oxycodone and remifentanil. Increases might reflect a change in the use of these substances. The increase in the usage of oxycodone and morphine may reflect the introduction on the market of new formulations.

- Forecasted (*Predicted*) Increases for 2010 (See Table 1).

We are forecasting for 2010 increases in the use (*predicted*) of D and DL amphetamine (9.4 percent), buprenorphine (18.5 percent), codeine (0.9 percent), diphenoxylate (0.3 percent), dronabinol (5.1 percent), ephedrine (6.4 percent), fentanyl (1.8 percent), hydrocodone (7.7 percent), hydromorphone (11.2 percent), methadone (0.05 percent), methylphenidate (4.3 percent), morphine (8.2 percent), oxycodone (12.2 percent), oxymorphone (15.7 percent), remifentanil (4.5 percent), temazepam (1.3 percent) and zolpidem (12.2 percent).

The *predicted* usage for amphetamine, cocaine, methylphenidate, and morphine for 2010 does not take under consideration specific needs of some manufacturers due to recent recalls of defective products or drug shortages. Recent recalls include, Shire's voluntary withdrawal of thirty-nine lots of the ADHD patch Daytrana (methylphenidate) on March 20, 2009 and Barr's voluntary recall of a lot of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate 20 mg tablets on August 13, 2009.

- New Drug Products and Supplemental Actions (See Table 2).

There were three new drug products containing Schedule II controlled substances approved in 2009 and two products within the first quarter of 2010. These products include codeine sulfate tablets (three strengths), fentanyl citrate buccal films (five strengths), hydromorphone hydrochloride extended release tablets (three strengths), morphine sulfate/naltrexone hydrochloride capsules (six strengths) and morphine sulfate oral solution (100mg/5 mL). A new product containing zolpidem tartrate (Schedule IV) was approved in March 13, 2009.

Two efficacy supplements containing hydromorphone and oxycodone were approved by the Agency in 2009. Purdue Pharmaceuticals Products obtained approval on April 30, 2009 for a supplemental new drug application providing additional strengths of Dilaudid (hydromorphone); additional dose strengths include 1, 2 and 4 mg/ml of hydromorphone. Xanodyne Pharmaceuticals received approval on May 15, 2009 for oxycodone 5 mg tablets, under the brand name Roxicodone.

A chemistry supplement providing for a formulation change for Duragesic fentanyl transdermal patches from a reservoir to a matrix design patch was approved on July 31, 2009. Due to this change, the amount of fentanyl required for manufacturing the 12.5 µgm/hr, 25 µgm/hr, 50 µgm/hr, 75 µgm/hr and 100 µgm/hr patches increased from (b) (4) per patch t(b) (4) respectively. On average the manufacturing of the reformulated patches will require (b) (4) the amount of fentanyl that was needed to maintain the manufacturing of the former reservoir patches.

A supplement for methylphenidate was approved in 2009. Novartis Pharmaceuticals Corporation received approval on October 23, 2009 for marketing the 30 mg extended release methylphenidate tablets (Focalin XR); accordingly permitting the removal of the 20 mg maximum dose restriction from the Focalin XR labeling.

Supplemental applications to expand the use of lisdexamphetamine in adolescents and for the use of GHB in fibromyalgia are under review, and actions for these applications are expected to take place in 2010.

- Generic Approvals (See **Table 3**).

During the period of January 2009-January 2010, the following generic products containing controlled substances received approval: one version of the *buprenorphine hydrochloride* sublingual tablet (two strengths), one version of the *fentanyl* transdermal system (extended release) (four strengths), two versions of the *fentanyl citrate* transmucosal lozenge (six strengths), two versions of the *hydromorphone hydrochloride* tablet (3 strengths), one version of the *meperidine hydrochloride* tablet (four strengths), one version of the *methadone hydrochloride* tablet (one strength), five versions of the *oxycodone hydrochloride* tablet (extended release) (seven strengths), two versions of the combination product *pseudoephedrine hydrochloride*/fexofenadine hydrochloride tablet (extended release) (two strengths) and one version of the *temazepam* capsule (three versions).

- Discontinued Products (See **Table 4**).

Distribution of the following products was discontinued during the time period January 2009- March 2010: one version of the combination product *amphetamine aspartate/amphetamine sulfate/dextroamphetamine saccharate/dextroampehetamine* sulfate tablet (4 strengths, all generic), three versions of the combination product of *codeine phosphate*/acetaminophen tablet (two strengths, all generic), two versions of the combination product *hydrocodone bitartrate*/homatropine methylbromide tablet and syrup (one strength, Hycodan) and tablet (one strength, generic), one version of the combination product *hydrocodone bitartrate*/acetaminophen capsule (one strength, generic Lorcet-HD), one version of the *hydromorphone hydrochloride* tablet (one strength, generic), one version of the *meperidine hydrochloride* tablet (one strength, Demerol), two versions of the *morphine sulfate* tablet extended release (one strength, generic), two versions of the combination product *pseudoephedrine hydrochloride*/ triprolidine hydrochloride tablet (one strength, generic) and one version of the combination product *pseudoephedrine hydrochloride*/brompheniramine maleate/*dextromethorphan hydrobromide* syrup (one strength, generic).

We hope that these data prove useful to the Drug Enforcement Administration in making quota determinations.

Sincerely,

Michael Klein, Ph.D
Director, Controlled Substance Staff
Office of the Center Director
Center for Drug Evaluation and Research

Concur:

Douglas C. Throckmorton, M.D.
Deputy Center Director
Center for Drug Evaluation and Research

Attachments:

Table 1: Forecast Uses (Purchases, in Kg) for 2009, 2010 and 2011, and Observed Use for 2007 and 2008 of Schedule II Controlled Substances.
Table 2: Recently Approved New Drug Products Containing Schedule II Controlled Substances.
Table 3: Recently Approved Generic Drug Products Containing Schedule II Controlled Substances.
Table 4: Drug Products Containing Schedule II Controlled Substances Discontinued in January 2008-February 2009.

Table 1: Forecast(*Predicted*) Uses (Purchases, in Kg) for 2010, 2011 and 2012, and Observed Use for 2008 and 2009 of Schedule II Controlled Substances. (*Note*: Substances for which either *observed* or *predicted* increases are equal to or exceed 10 percent are in bold).

SUBSTANCE	2008 Observed	2009 Observed (%CHANGE[1])	2010 Predicted (%CHANGE[2])	2011 Predicted (%CHANGE[3])	2012 Predicted (%CHANGE[4])
ALFENTANIL	0.42	0.45 (7.0)	0.42 (-7.3)	0.4 (3.5)	0.4 (3.4)
AMOBARBITAL	**2.18**	**4.53 (108.0)**	3.70 (-18.2)	2.9 (-20.6)	2.33 (-20.6)
***D-* & *DL-* AMPHETAMINE**	**6415.3**	**7493.0 (16.8)**	8193.27 (9.4)	8456.1 (3.2)	8718.9 (3.1)
BUPRENORPHINE	**930.9**	**1289.3 (38.5)**	**1527.7 (18.5)**	**1755.5 (14.9)**	**1968.6 (12.1)**
BUTORPHANOL	20.5	19.4 (-5.3)	18.56 (-4.3)	17.6 (-4.9)	16.7 (-5.2)
COCAINE	59.6	54.2 (-9.7)	41.9 (-22.7)	30.5 (-27.1)	19.1 (-37.2)
CODEINE	26288.6	25791.2 (-1.9)	26022.7 (0.9)	24981.3 (-4.0)	23938.5 (-4.2)
DIHYDROCODEINE	162.7	125.8 (-22.7)	93.3 (-25.8)	52.2 (-44.0)	11.1 (-78.1)
DIPHENOXYLATE	442.5	441.8 (-0.2)	443.3 (0.3)	443.2 (-0.01)	443.1 (-0.01)
DRONABINOL	86.2	92.0 (6.7)	96.6 (5.1)	103.1 (6.7)	109.6 (6.3)
EPHEDRINE	1455.2	1398.0 (-3.9)	1487.6 (6.4)	NA	NA
FENTANYL	491.1	490.1 (-0.2)	498.7 (1.8)	499.7 (0.2)	500.7 (0.2)
HYDROCODONE	52099.7	56810.9 (9.0)	61164.8 (7.7)	65775.5 (7.5)	70386.3 (7.0)
HYDROMORPHONE	**1130.0**	**1324.6 (17.2)**	**1472.6 (11.2)**	**1645.0 (11.7)**	**1817.4 (10.5)**
LEVORPHANOL	4.35	4.32 (-0.7)	4.2 (-1.3)	3.9 (-8.6)	3.5 (-9.4)
MEPERIDINE	3824.8	2932.1 (-23.3)	2358.8 (-19.6)	1624.5 (-31.1)	890.3 (-45.2)
METHADONE	7593.7	7782.0 (2.5)	7785.6 (0.05)	8087.9 (3.9)	8399.9 (3.9)
METHAMPHETAMINE	14.9	13.9 (-6.7)	13.1 (-5.6)	12.3 (-6.1)	11.52 (-6.5)
METHYLPHENIDATE	16697.9	17063.8 (2.2)	17796.8 (4.3)	18388.4 (3.3)	18980.0 (3.2)
MORPHINE	25270.5	27292.8 (8.0)	29519.7 (8.2)	31716.0 (7.4)	33912.3 (6.9)
OPIUM	557.9	87.1 (-84.4)	84.6 (-2.8)	77.2 (-8.7)	70.3 (-8.9)
OXYCODONE	**51343.6**	**57361.4 (11.7)**	**64346.2 (12.2)**	**71447.0 (11.0)**	78547.7 (9.9)

[1] 100 x [Observed (2009) - Observed (2008)]/Observed (2008); [2] 100 x [Forecast (2010) - Observed (2009)] /Observed (2009); [3] 100 x [Forecast (2011) - Forecast (2010)]/Forecast (2010); [4] 100 x [Forecast (2012) - Forecast (2011)]/Forecast (2011)

Table 1 Continued

SUBSTANCE	2008 Observed	2009 Observed (%CHANGE[1])	2010 Predicted (%CHANGE[2])	2011 Predicted (%CHANGE[3])	2012 Predicted (%CHANGE[4])
OXYMORPHONE	**897.5**	**1234.0 (37.5)**	**1427.2 (15.7)**	1322.0 (-7.4)	1224.6 (-7.4)
PENTAZOCINE	830.2	680.3 (-18.1)	522.0 (-23.3)	NA	NA
PENTOBARBITAL	96.5	95.0 (-1.6)	92.3 (-2.8)	80.3 (-13.0)	69.9 (-13.0)
PROPOXYPHENE	111743.7	102508.6 (-8.3)	95510.1 (-6.8)	86369.7 (-9.6)	77229.3 (-10.6)
PSEUDOEPHEDRINE	139915.6	132754.0 (-5.1)	129329.2 (-2.6)	NA	NA
REMIFENTANIL	0.85	0.8 (3.3)	0.9 (4.5)	0.9 (4.4)	1.0 (4.2)
SECOBARBITAL	**19.84**	**22.92 (15.5)**	21.5 (-5.9)	16.4 (-23.5)	12.6 (-23.5)
SUFENTANIL	0.08	0.08 (-1.7)	0.07 (-7.3)	0.08 (3.6)	0.08 (3.4)
TEMAZEPAM	6231.4	6383.9 (2.5)	6468.0 (1.3)	NA	NA
ZOLPIDEM	**10175.9**	**11564.40 (13.6)**	**12974.02 (12.2)**	**NA**	**NA**

[1] 100 x [Observed (2009) - Observed (2008)]/Observed (2008); [2] 100 x [Forecast (2010) - Observed (2009)] /Observed (2009); [3] 100 x [Forecast (2011) - Forecast (2010)]/Forecast (2010); [4] 100 x [Forecast (2012) - Forecast (2011)]/Forecast (2011)

Table 2: Recently Approved New Drug Products Containing Schedule II Controlled Substances.

DRUG PRODUCT	NDA #	DATE APPROVED	SPONSOR
CODEINE SULFATE - TABLET - 15 MG; 30 MG; 60 MG	22-402	07/16/09	ROXANE
DEXMETHYLPHENIDATE HYDROCHLORIDE (*FOCALIN*) - EXTENDED RELEASE CAPSULE - 30 MG	21-802	10/23/09	NOVARTIS
FENTANYL CITRATE (*ONSOLIS*) - BUCCAL FILM - EQ 0.2 MG; EQ 0.4 MG; EQ 0.6 MG; EQ 0.8 MG; EQ 1.2 MG	22-266	07/16/09	MEDA PHARM
HYDROMORPHONE HYDROCHLORIDE (*DILAUDID*) - INJECTABLE - 1MG/ML; 2MG/ML; 4MG/ML	19-034	04/30/09	PURDUE PHARM
HYDROMORPHONE HYDROCHLORIDE (*EXALGO*) - EXTENDED RELEASE TABLET - 8 MG; 12 MG; 16 MG	21-217	03/01/10	MALLINCKRODT
MORPHINE SUFATE - ORAL SOLUTION - 100MG/5ML	22-195	02/25/10	ROXANE
MORPHINE SULFATE / NALTREXONE HYDROCHLORIDE (*EMBEDA*) - CAPSULE - 20 MG/ 0.8 MG; 30 MG/ 1.2 MG; 50 MG/ 2 MG; 60 MG/ 2.4 MG; 80 MG/ 3.2 MG; 100 MG/ 4 MG	22-321	08/13/09	ALPHARMA KING
OXYCODONE HYDROCHLORIDE (*ROXICODONE*) - TABLET - 5 MG	21-011	05/15/09	XANODYNE PHARM
ZOLPIDEM TARTRATE (*EDULAR*) - SUBLINGUAL TABLET - 5 MG; 10 MG	21-997	03/13/09	MEDA PHARM

Table 3: Recently Approved Generic Drug Products Containing Schedule II Controlled Substances.

DRUG PRODUCT	ANDA #	DATE APPROVED	SPONSOR
BUPRENORPHINE HYDROCHLORIDE - SUBLINGUAL TABLET - EQ 2 MG; EQ 8 MG	78-633	10/08/09	ROXANE
FENTANYL - TRANSDERMAL FILM EXTENDED RELEASE - 25 MCG/HR; 50 MCG/HR; 75 MCG/HR; 100 MCG/HR	77-775	10/16/09	NOVEN
FENTANYL CITRATE - TRANSMUCOSAL LOZENGE - EQ 0.2 MG; EQ 0.4 MG; EQ 0.6 MG; EQ 0.8 MG; EQ 1.2 MG; EQ 1.6 MG	77-312	10/30/09	BARR
FENTANYL CITRATE - TRANSMUCOSAL LOZENGE - EQ 0.2 MG; EQ 0.4 MG; EQ 0.6 MG; EQ 0.8 MG; EQ 1.2 MG; EQ 1.6 MG	78-907	10/30/09	MALLINCKRODT
HYDROMORPHONE HYDROCHLORIDE - TABLET - 8 MG	77-471	12/09/09	LANNETT
HYDROMORPHONE HYDROCHLORIDE - TABLET - 2 MG; 4 MG	78-439	12/09/09	LANNETT
MEPERIDINE HYDROCHLORIDE - TABLET - 50 MG; 75 MG; 100 MG; 150 MG	40-893	06/24/09	MIKART
METHADONE HYDROCHLORIDE - TABLET - 10 MG	90-635	11/25/09	PHARMANET
OXYCODONE HYDROCHLORIDE - TABLET EXTENDED RELEASE - 80 MG	76-318	04/24/09	IMPAX LABS
OXYCODONE HYDROCHLORIDE - TABLET - 5 MG; 15 MG; 30 MG	90-659	04/10/09	SUN PHARMA
OXYCODONE HYDROCHLORIDE - TABLET - 5 MG; 15 MG; 30 MG	90-895	08/24/09	CORE PHARMA
OXYCODONE HYDROCHLORIDE - TABLET - 5 MG; 10 MG; 15 MG; 20 MG; 30 MG	91-393	08/31/09	AVANTHI INC

Table 3 Continued

DRUG PRODUCT	ANDA #	DATE APPROVED	SPONSOR
OXYCODONE HYDROCHLORIDE - TABLET - 5 MG	77-712	03/02/09	VINTAGE PHARM
PSEUDOEPHEDRINE HYDROCHLORIDE/ FEXOFENADINE HYDROCHLORIDE - EXTENDED RELEASE TABLET - 240 MG/ 180 MG; 120 MG/ 60 MG	79-043	11/17/09	DR REDDYS LABS LTD
PSEUDOEPHEDRINE HYDROCHLORIDE/ FEXOFENADINE HYDROCHLORIDE- EXTENDED RELEASE TABLET - 120 MG/ 60 MG	76-667	09/22/09	DR REDDYS LABS LTD
TEMAZEPAM - CAPSULE - 7.5 MG	78-581	09/08/09	MUTUAL PHARM
TEMAZEPAM - CAPSULE - 22.5 MG	77-175	09/14/09	MUTUAL PHARM
TEMAZEPAM - CAPSULE - 22.5 MG	70-920	06/12/2009	MYLAN

Table 4: Drug Products Containing Schedule II Controlled Substances Discontinued in January 2009-March 2010

DRUG PRODUCT	NDA/ ANDA#	DATE OF DISCONTINUATION	SPONSOR
AMPHETAMINE ASPARTATE / AMPHETAMINE SULFATE / DEXTROAMPHETAMINE SACCHARATE/ DEXTROAMPHETAMINE SULFATE - TABLET - 1.25 MG/ 1.25 MG/ 1.25 MG/ 1.25 MG; 2.5 MG/ 2.5 MG/ 2.5 MG/ 2.5MG; 5 MG/ 5 MG/ 5 MG/ 5 MG; 7.5 MG/ 7.5 MG/ 7.5 MG/ 7.5 MG	ANDA 40-456	1/09 - 3/10	WATSON LAB
CODEINE PHOSPHATE / ACETAMINOPHEN - TABLET - 30 MG/ 300 MG	ANDA 87-762	1/09 - 3/10	PHARMAERAL
CODEINE PHOSPHATE / ACETAMINOPHEN - TABLET - 30 MG/ 300 MG	ANDA 81-250	1/09 - 3/10	SANDOZ
CODEINE PHOSPHATE/ ACETAMINOPHEN - TABLET - 60 MG/ 300 MG	ANDA 87-762	1/09 - 3/10	SANDOZ
HYDROCODONE BITARTRATE / HOMATROPINE METHYLBROMIDE (*HYCODAN*) - TABLET AND SYRUP - 5 MG/ 1.5 MG AND 5 MG / 1.5 MG / 5 ML	NDA 05-213	1/09 - 3/10	ENDO PHARM
HYDROCODONE BITARTRATE / HOMATROPINE METHYLBROMIDE - TABLET - 5 MG/1.5 MG	ANDA 40-295	1/09 - 3/10	ACTAVIS TOTOWA
HYDROCODONE BITARTRATE / HOMATROPINE METHYLBROMIDE (*LORCET-HD*) - *CAPSULE* - 5 MG/ 500 MG	ANDA 87-336	1/09 - 3/10	MALLINCKRODT
HYDROMORPHONE HYDROCHLORIDE - TABLET - 4 MG	ANDA 74-597	05/09	ROXANE

Table 4 Continued

DRUG PRODUCT	NDA/ ANDA#	DATE OF DISCONTINUATION	SPONSOR
MEPERIDINE HYDROCHLORIDE (DEMEROL) - TABLET - 50 MG	NDA 05-010	02/10	SANOFI AVENTIS US
MORPHINE SULFATE – EXTENDED RELEASE TABLET - 15 MG; 30 MG; 60 MG	ANDA 74-862	1/09 - 3/10	PURDUE PHARM2
MORPHINE SULFATE – EXTENDED RELEASE TABLET - 100 MG; 200 MG	ANDA 74-769	1/09 - 3/10	PURDUE PHARM3
PSEUDOEPHEDRINE HYDROCHLORIDE / TRIPROLIDINE HYDROCHLORIDE - TABLET - 60 MG/ 2.5 MG	ANDA 88-602	1/09 - 3/10	SANDOZ
PSEUDOEPHEDRINE HYDROCHLORIDE / TRIPROLIDINE HYDROCHLORIDE - TABLET - 60 MG/ 2.5 MG	ANDA 88-193	1/09 - 3/10	SANDOZ
PSEUDOEPHEDRINE HYDROCHLORIDE / BROMPHENIRAMINE MALEATE / DEXTROMETHORPHAN HYDROBROMIDE - SYRUP - 30 MG/ 2 MG/ 10 MG/ 5 ML	ANDA 89-681	1/09 - 3/10	WOCKHARDT

2 Though the holder for these application changed in February 2010 from AB Generics to Purdue Pharma, Purdue did not reintroduce the product on the market and the product remains in the list of discontinued products..

3 Same as footnote 2 above.