DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

MAR 29 2012

Mr. Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Mr. Rannazzisi:

This is the response to your letter dated February 21, 2012, 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 2012 and 2013, 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 twenty-six Schedule II substances for the years 2012, 2013 and 2014. The Schedule II substances to be evaluated in this memorandum are: alfentanil, amobarbital, amphetamine, cocaine, codeine, difenoxin, dihydrocodeine, diphenoxylate, fentanyl, hydrocodone, hydromorphone, levorphanol, lisdexamfetamine, meperidine, methadone, methamphetamine, methylphenidate, morphine, opium, oxycodone, oxymorphone, pentobarbital, remifentanil, secobarbital, sufentanil, and tapentadol.

We also provide forecasts for the same years for ephedrine and pseudoephedrine. As in previous years, we are including the predicted usage of drug substances synthesized from the Schedule II precursor, thebaine. Production of these substances determines the quantities of thebaine produced. The drug substances derived from thebaine include naloxone, buprenorphine, and naltrexone. At the additional request of the DEA, we are providing forecasts on the usage of substances that are internationally controlled under the Psychotropic Convention. These drugs are buprenorphine, naloxone, naltrexone, pentazocine and zolpidem.

We are not providing forecasted usage for the following Schedule I and II substances: gamma-hydroxybutyric acid (GHB), levo-alpha-acetylmethadol (LAAM), nabilone, tetrahydrocannabinols, psilocybin, propiram, noroxymorphone and marijuana. Data regarding the usage of these substances are not available because they are either not currently marketed, or they are solely imported for use. Data is also unavailable for nonscheduled phenylpropanolamine which is not currently marketed in the U.S.A. The Schedule IV substance, clobazam, was just approved October, 21, 2011, and there is no usage data available. The other Schedule IV substances, diazepam, lorazepam, and midazolam, are also not included in this analysis because data is still being collected.

I. Forecasting Methodology

Monthly purchase data, which are the total of retail and non-retail sales for thirty-three 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 possible surrogates 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 2012, 2013 and 2014, 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 forecasted 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 2010 and 2011, 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 usage (purchases in kilograms) of the Schedule II substances are also provided in Table 1 for 2012, 2013 and 2014. The *observed* usage for 2010 and 2011 and *predicted* usage (purchases, in kilograms) for 2012, 2013, and 2014, for substances controlled under the Psychotropic Convention are provided in Table 2. The *observed* usage for 2010 and 2011, and *predicted* usage (purchases, in kilograms) for 2012, 2013, and 2014, for ephedrine and pseudoephedrine are provided in Table 3. Each predicted value is an estimate subject to variation.

The forecasts for the substances ephedrine, lisdexamfetamine, zolpidem, pentazocine, tapentadol and pseudoephedrine were restricted to only one year, due to limited data points.

We are providing current information on new drug products and abbreviated new drug applications for drug products containing Schedule II drugs approved in 2011, in Table 4 and Table 5.

In Table 6, we have listed products which were discontinued in 2011.

- Comments on *Observed* usages in 2011 (See Table 1, Table 2 and Table 3).

From 2010 to 2011, there was an increase in the *observed* usage for the following substances that is also *predicted* for 2012: alfentanil, ephedrine, levorphanol, lisdexamfetamine, methylphenidate, morphine, opium, and oxycodone. Most of the data received for 2011, were consistent with the data supplied in previous years except remifentanil and sufentanil. Substances noted in the previous reports with extreme percentage changes were amobarbital, diphenoxylate, meperidine, and difenoxin. These dramatic changes can be due to many factors including issues associated with data adjustments (correction factors) by the IMS.

- Forecasted (*Predicted*) Increases for 2012 (See Table 1, Table 2, and Table 3).

The *predicted* usage of these substances does not take under consideration specific needs of some manufacturers due to recent recalls of defective products or drug shortages. Recent recalls include ephedrine injection, Embeda® (morphine sulfate and naltrexone hydrochloride), butalbital, acetaminophen, and caffeine tablets, ephedrine injection, fentanyl transdermal patch, and hydrocodone bitartrate and acetaminophen tablets.

- Manufacturing issues that may affect the request for quotas by manufacturers and sponsors.

This section includes information as reported to the FDA by manufacturers on reformulations, recalls and manufacturing discontinuation.

On January 13, 2011, FDA asked manufacturers to limit the strength of acetaminophen in prescription drug products to 325 mg per tablet in order to reduce the risk of liver injury and allergic injuries. This initiative may impact future quotas for hydrocodone and oxycodone, because these opioids are generally used in combination with acetaminophen, and several of these combination products need to be reformulated.

On February 5, 2011, Qualitest Pharmaceuticals recalled three lots of hydrocodone bitartrate/acetaminophen 10/500 mg tablets.

Hospira discontinued production of ephedrine injection on February 8, 2011. Ephedrine injection is only produced by two other firms, Akorn and Sandoz.

Pfizer Inc. voluntarily recalled all dosage forms of Embeda® (morphine sulfate and naltrexone hydrochloride) extended release capsules on March 10, 2011, because a pre-specified stability requirement was not met during routine testing.

On June 27, 2011, Qualitest Pharmaceuticals and FDA notified pharmacists and patients of a recall to the retail level of specific lots of butalbital, acetaminophen, and caffeine tablets and hydrocodone bitartrate and acetaminophen tablets, due to the possibility that the recalled bottles may contain incorrect drug products.

- Products under development and recently approved supplements

One efficacy supplement was approved by the FDA in 2011, for Vyvanse (lisdexamfetamine) capsules for ADHD treatment in adults.

Two chemistry-manufacturing-control (CMC) supplements were approved by the FDA in 2011, for Daytrana (methylphenidate) transdermal patches.

INDs for products under development were submitted for the following products: A (b) (4) (b) (4)

There is one pending original NDA under review for methylphenidate ER powder for oral suspension.

We recommend that in the future you provide sufficient advance notice for new requests for estimates for medical, scientific and reserve stock needs for substances for the Schedule II quotas and your international assessment for the International Narcotics Control Board (INCB/UN). When you add new substances to your list that were not requested in previous years, note that there may be a delay in our response, as we need ample time for gathering and trending of data for new additions that lack comparative data from earlier years.

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 (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010 and 2011, of Schedule II Controlled Substances.
Table 2: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010 and 2011 of substances derived from thebaine and for substances controlled under the Psychotropic Convention
Table 3: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010 and 2011 of the substances ephedrine and pseudoephedrine
Table 4: Recently Approved New Drug Products Containing Schedule II Controlled Substances
Table 5: Recently Approved Generic Drug Products Containing Schedule II Controlled Substances
Table 6: Drug Products Containing Schedule II Controlled Substances Discontinued in 2011

Table 1: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010 and 2011, 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	2010 Observed	2011 Observed (%CHANGE[1])	2012 Predicted (%CHANGE[2])	2013 Predicted (%CHANGE[3])	2014 Predicted (%CHANGE[4])
ALFENTANIL	0.43	0.48 (12.1)	0.75 (55.0)	0.78 (3.3)	0.80 (3.2)
AMOBARBITAL	1.76	1.41 (-19.8)	1.10 (-22.4)	0.85 (-22.5)	0.66 (-22.5)
AMPHETAMINE	8560.50	9372.30 (9.5)	10054.91 (7.3)	10362.47 (3.1)	10670.02 (3.0)
COCAINE	53.9	48.70 (-9.7)	45.57 (-6.4)	43.18 (-5.3)	40.78 (-5.6)
CODEINE	23939.20	25053.40 (4.7)	24346.58 (-2.8)	23320.34 (-4.2)	22291.21 (-4.4)
DIFENOXIN	0.0002	0.06 (30600)	0.12 (98.1)	0.97 (700.9)	7.80 (700.9)
DIHYDROCODEINE	108.00	102.40 (-5.2)	89.18 (-12.9)	80.09 (-10.2)	71.00 (-11.4)
DIPHENOXYLATE	433.30	422.10 (-2.6)	417.59 (-1.1)	410.11 (-1.8)	402.63 (-1.8)
FENTANYL	497.10	526.60 (5.9)	549.25 (4.3)	585.72 (6.6)	624.61 (6.6)
HYDROCODONE	58813.90	62341.10 (6.0)	64217.68 (3.0)	66327.05 (3.3)	68436.41 (3.2)
HYDROMORPHONE	1445.60	1651.90 (14.3)	1726.60 (4.5)	1779.38 (3.1)	1832.89 (3.01)
LEVORPHANOL	0.13	0.30 (138.5)	0.91 (201.3)	0.70 (-23.0)	0.54 (-23.04)
LISDEXAMFETAMINE	9768.60	11730.00 (20.1)	14586.73 (24.4)	NA	NA
MEPERIDINE	2555.70	2277.00 (-10.9)	1947.86 (-14.5)	1711.47 (-12.1)	1475.08 (-13.81)
METHADONE	7784.10	7568.10 (-2.8)	7563.84 (-0.1)	7837.04 (3.6)	8115.35 (3.6)
METHAMPHETAMINE	13.33	12.35 (-7.4)	11.42 (-7.5)	10.49 (-8.1)	9.56 (-8.8)
METHYLPHENIDATE	17636.30	18185.50 (3.1)	18778.48 (3.3)	19364.24 (3.1)	19950.00 (3.0)
MORPHINE	28543.40	29909.90 (4.8)	31462.77 (5.2)	32865.06 (4.5)	34267.35 (4.3)
OPIUM	79.90	80.30 (0.5)	80.95 (0.8)	74.24 (-8.3)	67.95 (-8.5)
OXYCODONE	67311.20	69651.30 (3.5)	74613.90 (7.1)	77198.78 (3.5)	79612.63 (3.13)
OXYMORPHONE	1621.10	2596.60 (60.2)	3272.04 (26.0)	3129.19 (-4.4)	2991.84 (-4.4)
PENTOBARBITAL	85.40	79.10 (-7.4)	70.39 (-11.0)	61.28 (-12.9)	53.35 (-12.9)
REMIFENTANIL	0.89	1.04 (17.7)	1.20 (14.7)	1.44 (20.3)	1.73 (20.3)
SECOBARBITAL	21.90	19.60 (-10.5)	14.56 (-25.7)	11.16 (-23.3)	8.56 (-23.3)
SUFENTANIL	0.07	0.05 (-22.8)	0.03 (-45.0)	0.03 (2.5)	0.03 (3.2)
TAPENTADOL	2921.0	4902.1 (67.8)	6261.0 (27.7)	NA	NA

[1] 100 x [Observed (2011) - Observed (2010)]/Observed (2010); [2] 100 x [Forecast (2012) - Observed (2011)] /Observed (2011); [3] 100 x [Forecast (2013) - Forecast (2012)]/Forecast (2012); [4] 100 x [Forecast (2014) - Forecast (2013)]/Forecast (2013)

Table 2: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010 and 2011 of substances derived from thebaine and for substances controlled under the Psychotropic Convention (*Note*: Substances for which either *observed* or *predicted* increases are equal to or exceed 10 percent are in bold).

SUBSTANCE	2010 Observed	2011 Observed (%CHANGE[1])	2012 Predicted (%CHANGE[2])	2013 Predicted (%CHANGE[3])	2014 Predicted (%CHANGE[4])
BUPRENORPHINE	1556.30	1740.70 (11.9)	1899.16 (9.1)	2040.24 (7.4)	2173.36 (6.5)
NALOXONE	358.60	390.20 (8.8)	423.70 (8.6)	442.59 (4.5)	460.59 (4.1)
NALTREXONE	587.80	619.90 (5.5)	635.1 (2.5)	662.57 (4.3)	690.07 (4.2)
PENTAZOCINE	657.0	794.0 (20.9)	846.9 (6.6)	N/A	N/A
ZOLPIDEM	11885.80	12202.40 (2.7)	12634.20 (3.5)	N/A	N/A

[1] 100 x [Observed (2011) - Observed (2010)]/Observed (2010); [2] 100 x [Forecast (2012) - Observed (2011)] /Observed (2011); [3] 100 x [Forecast (2013) - Forecast (2012)]/Forecast (2012); [4] 100 x [Forecast (2014) - Forecast (2013)]/Forecast (2013)

Table 3: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010 and 2011 of the substances ephedrine and pseudoephedrine.

SUBSTANCE	2010 Observed	2011 Observed (%CHANGE[1])	2012 Predicted (%CHANGE[2])	2013 Predicted (%CHANGE[3])	2014 Predicted (%CHANGE[4])
EPHEDRINE	1477.00	1532.60 (3.8)	1648.77 (7.6)	1745.38 (5.9)	NA
PSEUDOEPHEDRINE	119421.8	100674.10 (-15.7)	94953.24 (-5.7)	73755.03 (-22.3)	NA

[1] 100 x [Observed (2011) - Observed (2010)]/Observed (2010); [2] 100 x [Forecast (2012) - Observed (2011)] /Observed (2011); [3] 100 x [Forecast (2013) - Forecast (2012)]/Forecast (2012); [4] 100 x [Forecast (2014) - Forecast (2013)]/Forecast (2013)

Table 4: Recently Approved New Drug Products Containing Schedule II Controlled Substances

DRUG PRODUCT	NDA	DATE APPROVED	SPONSOR
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE (*FIORICET WITH CODEINE*) – CAPSULE - 325MG; 50MG; 40MG; 30MG	20-232	06/22/11	WATSON
CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE (*ZUTRIPRO*) – ORAL SOLUTION - 4MG/5ML; 5MG/5ML; 60MG/5ML	22-439	06/08/11	CYPRESS
CODEINE SULFATE – ORAL SOLUTION – 30 MG/5 ML	202-245	06/30/11	ROXANE
FENTANYL (SUBSYS) – SUBLINGUAL SPRAY – 0.1 MCG; 0.2 MCG; 0.4 MCG; 0.6 MCG; 0.8 MCG	202-788	01/04/12	INSYS
FENTANYL CITRATE (*ABSTRAL*) – SUBLINGUAL TABLET - EQ 0.1 MG; EQ 0.2 MG; EQ 0.3 MG; EQ 0.4 MG; EQ 0.6 MG; EQ 0.8	22-510	01/07/11	PROSTRAKAN
FENTANYL CITRATE (*LAZANDA*) – NASAL SPRAY – EQ 0.1 MG BASE; 0.4 MG BASE	22-569	06/30/11	ARCHIMEDES
HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE (*REZIRA*) – ORAL SOLUTION - 5MG/5ML; 60MG/5ML	22-442	06/08/11	CYPRESS
HYDROMORPHINE – INJECTION – 1 MG/ML; 2 MG/ML; 4 MG/ML	200-403	12/1/11	HOSPIRA
METHYLPHENIDATE HYDROCHLORIDE – TABLET – 5MG; 10 MG; 20 MG	90-710	3/14/12	SUN
MORPHINE SULFATE – INJECTION – 2 MG/ML; 4 MG/ML; 8 MG/ML; 10 MG/ML; 12 MG/ML; 15 MG/ML	202-515	11/14/11	HOSPIRA
MORPHINE SULFATE – ORAL SOLUTION – 20 MG/ML	201-517	06/23/11	LANNETT
OXYCODONE HYDROCHLORIDE (*OXECTA*) – TABLET – 5 MG; 7.5 MG	202-080	06/17/11	KING
OXYCODONE HYDROCHLORIDE – ORAL SOLUTION – 5 MG/ 5 ML	201-194	01/12/12	VISTAPHARM
OXYMORPHONE (*OPANA ER*) – EXTENDED RELEASE TABLET – 5 MG; 7.5 MG; 10 MG; 15 MG; 20 MG; 30 MG AND 40 MG	201-655	12/09/11	ENDO

Table 5: Recently Approved Generic Drug Products Containing Schedule II Controlled Substances

DRUG PRODUCT	ANDA #	DATE APPROVED	SPONSOR
ACETAMINOPHEN AND CODEINE PHOSPHATE – ORAL SOLUTION - 120 MG/5 ML; 12 MG/5 ML	91-238	11/10/11	VINTAGE
FENTANYL - EXTENDED RELEASE TRANSDERMAL FILM - 25 MCG/HR; 50 MCG/HR; 75 MCG/HR; 100 MCG/HR	77-154	02/09/11	MALLINCKRODT
FENTANYL CITRATE - BUCCAL TABLET – EQ 0.1 MG BASE, EQ 0.2 MG BASE, EQ 0.4 MG BASE, EQ 0.6 MG BASE, EQ 0.8 MG BASE	79-075	01/07/11	WATSON
HYDROCODONE BITARTRATE AND ACETAMINOPHEN - TABLET – 300 MG/5 MG; 300 MG/7.5 MG; 300 MG/10 MG	90-415	01/24/11	BOCA
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – ORAL SOLUTION – 7.5 MG/ 325 MG PER 15 ML	200-343	01/25/12	VISTAPHARM
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – ORAL SOLUTION – 7.5 MG/ 325 MG PER 15 ML	40-894	07/19/11	BOCA
HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE– TABLET - 1.5 MG/5 MG	91-528	04/20/11	NOVEL
MORPHINE SULFATE – ORAL SOLUTION – 10 MG/5 ML AND 20 MG/5ML	201-947	01/05/12	VISTAPHARM
MORPHINE SULFATE – ORAL SOLUTION – 100 MG/5 ML	202-348	07/15/11	MALLINCKRODT
MORPHINE SULFATE – EXTENDED RELEASE TABLET – 15 MG; 30 MG; 60 MG; 100 MG; 200 MG	200-824	10/18/11	MYLAN
MORPHINE SULFATE – EXTENDED RELEASE CAPSULE – 20 MG; 30 MG; 50 MG; 60 MG; 80 MG; 100 MG	200-812	11/10/11	WATSON
OXYCODONE HYDROCHLORIDE– EXTENDED RELEASE TABLET - 10 MG; 20 MG; 40 MG; 80 MG	77-822	01/03/11	MALLINCKRODT
OXYCODONE HYDROCHLORIDE – TABLET - 5 MG; 10 MG; 15 MG; 20 MG; 30 MG	91-490	03/09/11	RHODES
OXYCODONE HYDROCHLORIDE – TABLET – 5 MG; 15 MG; 30 MG	202-116	12-30-11	ALVOGEN
OXYCODONE AND ASPIRIN – TABLET – 4.8355 MG/325 MG	91-670	03/16/11	COASTAL

OXYCODONE AND ASPIRIN – TABLET – 4.8355 MG/325 MG	90-084	03/22/11	WATSON
OXYCODONE HYDROCHLORIDE - TABLET - 5 MG; 15 MG; 30 MG	91-313	02/18/11	COASTAL
OXYCODONE HYDROCHLORIDE - TABLET - 5MG; 10 MG; 15 MG; 20 MG; 30 MG	91-490	03/09/11	RHODES
OXYCODONE HYDROCHLORIDE AND ASPIRIN - TABLET - 325MG/4.8355 MG	91-670	03/16/11	COASTAL
OXYCODONE HYDROCHLORIDE AND ASPIRIN - TABLET - 325MG/4.8355 MG	90-084	03/22/11	WATSON
OXYMORPHONE HYDROCHLORIDE - TABLET - 5MG; 10 MG	91-443	02/15/11	TEVA
OXYMORPHONE HYDROCHLORIDE - TALBET - 5MG; 10MG	90-964	09/27/10	ROXANE
OXYMORPHONE HYDROCHLORIDE - EXTENDED RELEASE TABLET- 5 MG; 7.5 MG; 10 MG; 15 MG; 20 MG; 30 MG; 40 MG	79-087	12/21/10	IMPAX
OXYMORPHONE HYDROCHLORIDE - EXTENDED RELEASE TALBET - 7.5 MG; 15 MG	79-046	12/13/10	ACTAVIS

Table 6: Drug Products Containing Schedule II Controlled Substances Discontinued in 2011

DRUG PRODUCT	NDA/ ANDA#	DATE OF DISCONTINUATION	SPONSOR
AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE – TABLET – 5 MG; 7.5 MG; 10 MG; 12.5 MG; 15 MG; 20 MG; 30 MG	40-440	09/01/11	MALLINCKRDOCT
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/ 15 MG; 300 MG/ 30 MG; 300 MG/ 60 MG	40-419	12/01/11	DURAMED
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/ 15 MG	70-145	12/01/11	MALLINCKRODT
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/15 MG	89-997	8/01/11	WATSON
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/30 MG	89-998	08/01/11	WATSON
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/ 60 MG	89-999	08/01/11	WATSON
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/ 15 MG; 300 MG/ 30 MG; 300 MG/ 60 MG	40-223	09/01/11	BARR
CODEINE PHOSPHATE AND ACETAMINOPHEN – TABLET – 300 MG/15 MG; 300 MG/30 MG; 300 MG/60 MG	40-443	07/01/11	WATSON
CODEINE PHOSPHATE AND ACETAMINOPHEN– ORAL SOLUTION – 120MG/5ML; 12 MG/5 ML	85-861	8/01/11	ACTAVIS
CODEINE PHOSPHATE AND ACETAMINOPHEN – ORAL SUSPENSION – 120MG/5ML; 12 MG/5 ML	85-883	8/01/11	ACTAVIS
DIHYDROCODEINE BITARTRATE, CAFFEINE AND ACETAMINOPHEN – TABLET – 712.8 MG/ 60 MG/ 32 MG	40-637	08/01/11	WEST-WARD
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – ORAL SOLUTION – 10 MG/ 500 MG PER 15 ML	40-508	11/01/11	MALLINCKRODT
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 7.5 MG/ 750 MG	40-822	08/01/11	WATSON
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 7.5 MG/ 325 MG; 10 MG/ 325 MG	40-248	07/01/11	WATSON
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 500 MG/5 MG	40-493	07/01/11	WATSON
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 750 MG/7.5 MG	40-494	07/01/11	WASTSON
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET - 500 MG/ 2.5 MG; 500 MG/ 7.5 MG; 650 MG/ 7.5 MG; 650 MG/ 10 MG	40-123	08/01/11	WATSON

HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 325 MG/10 MG	40-826	05/01/11	RANBAXY
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 500 MG/5 MG	40-825	05/01/11	RANBAXY
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 500 MG/10 MG	40-824	05/01/11	RANBAXY
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – ORAL SOLUTION – 500 MG/15 ML; 10 MG/ 15 ML	40-680	11/01/11	MALLINCKRODT
HYDROCODONE BITARTRATE AND ACETAMINOPHEN – TABLET – 750 MG/ 7.5 MG	40-822	05/01/11	RANBAXY
LEVORPHANOL TARTRATE – TABLET – 2 MG	087-20	03/01/11	VALEANT
METHYLPHENIDATE HYDROCHLORIDE – EXTENDED RELEASE TABLET – 20 MG	75-450	08/01/11	ACTAVIS
METHYLPHENIDATE HYDROCHLORIDE – TABLET – 5 MG; 10 MG; 20 MG	40-321	08/01/11	ACTAVIS
MORPHINE SULFATE – INJECTION – 10 MG/ML	21-671	05/01/11	EKR
MORPHINE SULFATE – EXTENDED RELEASE TABLET – 100 MG	75-656	08/01/11	WATSON
MORPHINE SULFATE AND NALTREXONE *(EMBEDA)* - EXTENDED RELEASED 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	3/01/11	ALPHARMA KING
OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN – ORAL SOLUTION – 325 MG/5ML; 5MG/ 5ML	40-223	11/01/11	MALLINCKRODT
OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN – ORAL SOLUTION – 325 MG/5ML PER 15 ML	40-680	07/01/11	MALLINCKRODT
OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN – CAPSULE – 500 MG/ 5 MG	40-199	07/01/11	ACTAVIS
OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN - CAPUSLE – 325 MG/5 MG	40-203	7/01/11	ACTAVIS
OXYCODONE HYDROCHLORIDE AND IBUPROFEN – TABLET – 400 MG/ 5 MG	21-378	10/01/11	FOREST
OXYMORPHONE *(OPANA)* - EXTENDED RELEASE TABLET - 7.5 MG; 15 MG	21-610	2/01/11	ENDO
PROPOXYPHENE HYDROCHLORIDE – CAPSULE – 65 MG	80-530	08/01/11	HERITAGE
PROPOXYPHENE HYDROCHLORIDE – CAPSULE – 65 MG	40-569	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE – CAPSULE – 65 MG	80-269	01/01/10	PAR
PROPOXYPHENE HYDROCHLORIDE – CAPSULE – 65 MG	88-615	03/01/11	TEVA
PROPOXYPHENE HYDROCHLORIDE– CAPSULE – 65 MG	40-908	03/01/11	VINTAGE
PROPOXYPHENE HYDROCHLORIDE– CAPSULE – 65 MG	83-501	01/01/11	WEST WARD

PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/01/11	MYLAN
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/ 65 MG	83-978	08/11	MYLAN
PROPOXYPHENE NAPSYLATE – TABLET – 100 MG	16-862	01/01/11	XANODYNE
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET – 325 MG/ 50 MG; 650 MG/ 100 MG	77-677	08/11	WOCKHARDT
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN (*DARVOCET N 50/100*) – TABLET – 650 MG/100 MG; 325 MG/50MG	17-122	01/01/11	XANODYNE
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET- 650MG/100MG; 325MG/50 MG; 325MG/100 MG	74-843	03/01/11	VINTAGE
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET- 325MG/100 MG	76-743	03/01/11	VINTAGE
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET- 500 MG/100 MG	76-750	03/01/11	CORNERSTONE
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET- 650 MG/100 MG	74-119	03/01/11	TEVA
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET -650 MG/ 100 MG	70-145	12/01/11	MYLAN
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN – TABLET – 650 MG/100 MG	77-821	04/01/11	MIRROR
PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN – TABLET – 650 MG/65 MG	40-507	03/01/11	VINTAGE
PROPOXYPHENE HYDROCHLORIDE (*DARVON*) – CAPSULE – 65 MG	10-997	01/01/11	XANODYNE