DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

APR 10 2013

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 January 14, 2013, 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 2013 and 2014, 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-five Schedule II substances for the years 2013 and 2014. The Schedule II substances to be evaluated in this memorandum are: alfentanil, amobarbital, amphetamine, cocaine, codeine, dihydrocodeine, diphenoxylate, fentanyl, hydrocodone, hydromorphone, lisdexamfetamine, meperidine, methadone, methamphetamine, methylphenidate, morphine, nabilone, 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 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 include: alprazolam, buprenorphine, clonazepam, diazepam, diethylpropion, lorazepam, midazolam, temazepam, and zolpidem.

I. Forecasting Methodology

Monthly purchase 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™ database 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 sampling and non-sampling errors. The IMS Health, National Sales Perspectives™ database 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.

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 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.

The forecasting method relies on a mathematical model that is accurate only to the extent that the environment of the drug use system remains essentially the same as in previous years. This year, two smoothing approaches are used to minimize errors in forecasting. The decision to use one approach over the other is based on the characteristics of the data used to make the projections. For substances that exhibited no apparent usage trend or a trend that is characterized by sharp changes or recent inconsistencies, simple exponential smoothing is used and forecasts are only provided for 2013. The latter may be characterized by either a small number of data points or low stability in an increasing or decreasing trend or both. For substances with a well-defined increasing or decreasing trend, a linear exponential smoothing method is used.

II. Tabular Data

The *observed* usage (purchases in kilograms) of Schedule II substances in 2010, 2011, and 2012, 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 2013 and 2014. The *observed* usage for 2010, 2011, and 2012 and *predicted* usage (purchases, in kilograms) for 2013 and 2014 for substances controlled under the Psychotropic Convention are provided in **Table 2**. The *observed* usage for 2010, 2011, and 2012 and *predicted* usage (purchases, in kilograms) for 2013 and 2014

for ephedrine and pseudoephedrine are provided in **Table 3.** Each predicted value is an estimate subject to variation.

Among the 49 substances requested by DEA, we are not providing forecasted usage for the following Schedule I and II substances: difenoxin, etorphine, gamma-hydroxybutyrate (GHB) or sodium oxybate, levorphanol, marijuana, noroxymorphone, propiram, psilocybin, and tetrahydrocannabinols because data regarding the usage of these substances were not available or limited. Data was also unavailable for phenylpropanolamine. The Schedule IV substance clobazam was also not included in this analysis because data are only available for 2012, since the drug was approved in October 2011. There were data gaps for difenoxin and levorphanol in which no sales data were available for varying time periods.

We are providing current information on new drug applications and abbreviated new drug applications for products containing Schedule II drugs approved between January 2012 and March 2013, in **Table 4** and **Table 5.**

In **Table 6,** we have listed products which were discontinued between January 2012 and December 2012.

- Comments on *Observed* usages in 2012 (See **Table 1, Table 2 and Table 3).**

From 2011 to 2012, there was an increase in the *observed* usage for the following substances that is also *predicted* for 2013: amphetamine, fentanyl, hydromorphone, lisdexamfetamine, methylphenidate, morphine, remifentanil, and tapentadol.

Most of the data received this year were consistent with the data supplied in previous years except amphetamine, hydromorphone, lisdexamfetamine and tapentadol. The usage for these substances changed dramatically (e.g. increased $\geq$ 10%) from 2011 to 2012, and the *predicted* usage in 2013 is $\geq$ 10% of the observed 2012 values. Dihydrocodeine and pentobarbital displayed relatively large decreases in both *observed* usage in 2012, and *predicted* usage in 2013.

The *observed* retail and non-retail sales values for some substances were inconsistent with previous years. This is a result of regular data corrections and updates by the IMS data investigation team. Substances noted in the previous reports with extreme values were amobarbital, diphenoxylate, meperidine, and difenoxin. As stated in previous reports, most of these corrections were minor (e.g., $\leq$0.5%) and should not be an influencing factor in the current assessment. Similar discrepancies were also noted and resolved in previous reports.

- Forecasted (*Predicted*) Increases for 2013 (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. 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 quotas for hydrocodone and oxycodone, because these Schedule II substances are used in many products in combination with

acetaminophen, and several of these combination products need to be reformulated.

An efficacy supplement was approved for Vyvanse (lisdexamfetamine) capsules for an ADHD maintenance study in adults.

Investigational new drug applications were submitted for the following approved drugs, and may require additional drug quantities for large clinical trials: (b) (4) (b) (4)

In September 2012, there were recalls of hydrocodone and acetaminophen tablets by Watson Laboratories and by Qualitest. The recalls included the following:

- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg with the expiry date April 2014.
- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg, expiry date December 2013.

In August 2012, there was a recall of one lot of hydromorphone hydrochloride injectable by Hospira. The affected product is a prefilled glass cartridge for use with the Carpuject Syringe system. The expiration date is December 1, 2013.

Several lots of Daytrana (methylphenidate transdermal patch) were recalled due to skin adherence problems. The Sponsor has (b) (4) (b) (4)

Based on increased demand, manufacturing delays, and shortages in 2012, the Drug Shortages Division predicts additional quota demands in 2013 for the following substances: alfentanil, amphetamine, fentanyl, hydromorphone, meperidine, methadone, methylphenidate, morphine, oxymorphone, sufentanil, buprenorphine, diazepam, lorazepam, midazolam, naloxone, and naltrexone.

We hope that these data prove useful to the Drug Enforcement Administration in making quota determinations. If you have any questions or need additional clarification, please [redacted], Ph.D., Controlled Substance Staff, at 301-796-5402.

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 Director for Regulatory Programs
Center for Drug Evaluation and Research

Attachments:

Table 1: Forecast Uses (Purchases, in Kg) for 2013 and 2014, and Observed Use for 2010, 2011, and 2012 of Schedule II Controlled Substances.

Table 2: Forecast Uses (Purchases, in Kg) for 2013 and 2014, and Observed Use for 2010, 2011, and 2012, of substances derived from thebaine and for substances controlled under the Psychotropic Convention.

Table 3: Forecast Uses (Purchases in Kg) for 2013, and 2014, and Observed Use for 2010, 2011, and 2012 of the substance 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 between January 2012 and December 2012.

Table 1: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2013 and 2014, and Observed Use for 2010, 2011, and 2012, of Schedule II Controlled Substances. (*Note*: Substances for which either 2012 *observed* or 2013 and 2014 *predicted* increases are equal to or exceed 10 percent are in bold).

SUBSTANCE	2010 Observed	2011 Observed (%CHANGE[1])	2012 Observed (%CHANGE[2])	2013 Predicted (%CHANGE[3])	2014 Predicted (%CHANGE[4])
ALFENTANIL	0.43	**0.49 (14.0)**	0.40 (-18.4)	**0.44 (10.14)**	N/A
AMOBARBITAL	1.76	1.41(-19.9)	1.55 (9.9)	1.09 (-29.7)	N/A
AMPHETAMINE	8561.5	9401.30 (-9.8)	**10671.30 (13.5)**	**11811.93 (10.7)**	12962.96 (-9.7)
COCAINE	53.90	48.70 (-9.6)	43.80 (-10.1)	39.17 (-10.6)	34.49 (-11.9)
[redacted]	**23959.50**	**25149.10 (5.0)**	**22687.00 (-9.8)**	22401.85 (-1.3)	**N/A**
DIHYDROCODEINE	108.00	102.60 (-5.0)	71.00 (-30.8)	41.43 (-41.6)	**11.83 (-71.4)**
DIPHENOXYLATE	433.60	423.70 (-2.3)	382.70 (-9.7)	382.74 (0.0)	N/A
FENTANYL	497.20	528.30 (6.3)	572.50 (8.4)	616.70 (7.7)	660.85 (7.2)
HYDROCODONE	58844.00	62535.70 (6.3)	62447.70 (-0.1)	63496.96 (1.7)	64455.56 (1.5)
HYDROMORPHONE	1445.90	**1658.20 (14.7)**	**1901.80 (14.7)**	**2124.81 (11.7)**	**2350.04 (10.6)**
LISDEXAMFETAMINE	9769.10	**11749.90 (20.3)**	**13398.30 (14.0)**	**15099.10 (12.7)**	**16797.85 (11.3)**
MEPERIDINE	2555.80	2282.40 (-10.7)	1868.30 (-18.1)	1484.33 (-20.6)	1098.43 (-26.0)
METHADONE	7808.80	7589.20 (-2.8)	7131.10 (-6.0)	6673.48 (-6.4)	N/A
METHAMPHETAMINE	13.33	12.45 (-6.6)	12.85 (3.2)	12.85 (0.0)	N/A
METHYLPHENIDATE	17637.40	18222.00 (3.3)	18733.00 (2.8)	19245.43 (2.7)	19757.85 (2.7)
MORPHINE	28543.80	29980.90 (5.0)	30519.00 (1.8)	31097.24 (1.9)	31675.02 (1.9)
NABILONE	0.05	0.05 (0.0)	0.04 (-20.0)	0.04 (0.0)	N/A
OPIUM	79.90	80.60 (0.9)	77.20 (-4.2)	74.75 (-3.2)	N/A
OXYCODONE	67353.20	69894.70 (3.8)	66728.10 (-4.5)	66731.26 (0.0)	N/A
OXYMORPHONE	1621.40	2604.20 (60.6)	1913.80 (-26.5)	1914.49 (0.0)	N/A
PENTOBARBITAL	85.40	79.10 (-7.4)	46.80 (-40.8)	22.78 (-51.3)	N/A
REMIFENTANIL	0.89	1.04 (16.9)	1.12 (7.7)	1.21 (8.0)	1.30 (7.4)
SECOBARBITAL	22.00	19.60 (-10.9)	15.40 (-21.4)	11.20 (-27.3)	N/A
SUFENTANIL	0.07	0.05 (-28.6)	0.05 (0.0)	0.04 (-20.0)	N/A
[redacted]	**2921.50**	**4922.70 (68.5)**	**6248.50 (26.9)**	**7575.65 (21.2)**	**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 2: Forecast (*Predicted*) Uses (Purchases, in Kg) for 2012, 2013 and 2014, and Observed Use for 2010, 2011, and 2012 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	2011 Observed (%CHANGE[1])	2012 Predicted (%CHANGE[2])	2013 Predicted (%CHANGE[3])	2014 Predicted (%CHANGE[4])
[redacted]ZOLAM	2261.30	2341.70 (3.6)	2275.30 (-2.8)	2275.37 (0.0)	N/A
BUPRENORPHINE	**1556.6**	**1745.00 (12.1)**	**2008.60 (15.1)**	**2272.05 (13.1)**	**2535.50 (11.6)**
CLONAZEPAM	1347.10	1406.60 (4.4)	1425.70 (1.4)	1451.45 (1.8)	1476.93 (1.8)
DIAZEPAM	5039.20	5108.00 (1.4)	4912.30 (-3.8)	4912.50 (0.0)	N/A
DIETHYLPROPION	699.60	601.50 (-14.0)	544.80 (-9.4)	477.47 (-12.4)	410.99 (-13.9)
LORAZEPAM	1353.00	1387.00 (2.5)	1351.40 (2.6)	1351.44 (0.0)	N/A
MIDAZOLAM	901.00	675.60 (-25.0)	314.90 (-53.0)	315.26 (0.1)	N/A
NALOXONE	358.70	390.80 (8.9)	**438.70 (12.3)**	**486.57 (10.9)**	534.44 (9.8)
NALTREXONE	587.80	621.80 (5.8)	630.30 (1.4)	640.22 (1.6)	650.13 (1.5)
TEMEZAPAM	6499.90	6582.10 (1.3)	6392.40 (-2.9)	6392.59 (0.0)	N/A
ZOLPIDEM	11888.40	12227.60 (2.9)	12050.70 (-1.4)	11920.25 (-1.1)	11788.75 (-1.1)

[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 2013 and 2014, and Observed Use for 2010 and 2011, and 2012 of ephedrine and pseudoephedrine (*Note*: Substances for which either *observed* or *predicted* increases are equal to or exceed 10 percent are in bold).

SUBSTANCE	2010	2011 Observed (%CHANGE[1])	2012 Predicted (%CHANGE[2])	2013 Predicted (%CHANGE[3])	2014 Predicted (%CHANGE[4])
EPHEDRINE	1476.90	1534.20 (3.9)	**1973.90 (28.7)**	**2289.19 (16.0)**	NA
PSEUDOEPHEDRINE	**119448.80**	101137.30 (-15.3)	92883.40 (-8.2)	79865.15 (-14.0)	67519.27 (-15.5)

[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
FENTANYL (SUBSYS) – SUBLINGUAL SPRAY – 0.1 MCG; 0.2 MCG; 0.4 MCG; 0.6 MCG; 0.8 MCG, 1.2 MCG, 1.6 MCG	202-788	01/04/12	INSYS
OXYCODONE HYDROCHLORIDE – ORAL SOLUTION – 5 MG/ 5 ML	201-194	01/12/12	VISTAPHARM
METHYLPHENIDATE EXTENDED RELEASE POWDER	202-100	09/27/2012	NEXT WAVE PHARMACEUTICALS

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

DRUG PRODUCT	ANDA #	DATE APPROVED	SPONSOR
HYDROCODONE BITARTRATE AND ACETAMINOPHEN ORAL SOLUTION - 7.5 MG/ 325 MG per 15 ML	200343	01/25/12	VISTAPHARM
[redacted] ORAL SOLUTION - 10 MG/5 ML and 20 MG/5ML	201947	01/05/12	VISTAPHARM
BUTALBITAL, ACETAMINOPHEN, CAFFEINE AND CODEINE PHOSPHATE USP - 50 MG/300 MG/40 MG/30 MG	76560	7/19/2012	NEXGEN PHARMA
HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS USP, 5 MG/325 MG, 7.5 MG/325 MG AND 10 MG/325 MG	201013	4/11/2012	AUROLIFE
OXYCODONE AND ACETAMINOPHEN TABLETS USP, 7.5 M/325 MG AND 10 MG/325 MG	040800	4/3/12	ACTAVIS TOTOWA
OXYCODONE AND ACETAMINOPHEN TABLETS USP, 7.5 MG/325 MG AND 10 MG/325 MG	202677	7/26/12	ALVOGEN
DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES - 5 MG, 10 MG, 15 MG, 20 MG, 25 MG AND 30 MG	077302	6/22/12	ACTAVIS ELIZABETH LLC
AMPHETAMINE SULFATE TABLETS - 5 MG AND 10 MG	200166	8/9/12	ARBOR
CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE [redacted] TABLETS USP - 5 [redacted]	090922	9/28/12	SUN PHARMACEUTICAL INDUSTRIES LTD.
HYDROCODONE POLISTIREX AND CHLORPHENIRAMINE POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION - 10 MG/8 MG PER 5 ML	091671	6/29/12	CORNERSTONE THERAPEUTICS
PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE SYRUP - 6.25 MG AND 10 MG/5 ML	200386	6/29/12	TRIS PHARMA INC
DEXTROAMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES - 5 MG, 10 MG AND 15 MG	203901	11/30/12	ACTAVIS ELIZABETH LLC
LORAZEPAM ORAL CONCENTRATE USP - 2 MG/ML	200169	1/30/12	HI-TECH PHARMA CO

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES - 10 MG, 20 MG, 30 MG AND 40 MG	079031	7/13/12	BARR LABORATORIES
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES - 10 MG, 20 MG AND 30 MG	077707	7/16/12	TEVA PHARMACEUTICALS
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES - 40 MG, 50 MG AND 60 MG	078873	7/19/12	TEVA PHARMACEUTICALS
METHYLPHENIDATE HYDROCHLORIDE TABLETS USP - 5 MG, 10 MG AND 20 MG	090710	3/15/12	SUN PHARMACEUTICALS
[redacted] METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE TABLETS USP - 27 MG, 36 MG AND 54 MG	202608	12/28/12	MALLINCKRODT INC
MIDAZOLAM INJECTION USP - 1 MG/ML; 2 MG/2 ML SINGLE-DOSE VIALS	090606	2/19/12	GLAND PHARMA LIMITED
MIDAZOLAM HYDROCHLORIDE INJECTION - 5 MG (BASE)/ML; 25 (BASE)/5 ML AND 50 MG (BASE)/10 ML	090850	1/25/12	GLAND PHARMA LIMITED
MORPHINE SULFATE EXTENDED-RELEASE CAPSULES USP - 30 MG, 45 MG, 60 MG, 75 MG, 90 MG AND 120 MG	079040	1/16/13	ACTAVIS ELIZABETH LLC
MORPHINE SULFATE ORAL SOLUTION - 100 MG/5 ML (20 MG/ML)	201574	8/6/12	PADDOCK LABORATORIES
MORPHINE SULFATE EXTENDED-RELEASE TABLETS – 15 MG, 30 MG, 60 MG, 100 MG AND 200 MG	078761	5/11/12	RANBAXY LABORATORIES LIMITED
NALTREXONE HYDROCHLORIDE TABLETS USP - 50 MG	0903356	2/24/12	SUN PHARMA GLOBAL FZE
[redacted] HYDROCHLORIDE CAPSULES - 5 MG	203107	7/26/12	COASTAL PHARMACEUTICALS
OXYCODONE HYDROCHLORIDE ORAL SOLUTION USP - 100 MG/5 ML (20 MG/ML)	202537	7/30/12	VISTAPHARM INC
OXYCODONE HYDROCHLORIDE TABLETS USP -5 MG, 15 MG AND 30 MG	202160	11/19/12	AUROLIFE PHARMA INC
OXYCODONE HYDROCHLORIDE TABLETS USP - 10 MG AND 20 MG	090659	11/6/12	SUN PHARMA INDS INC
TEMAZEPAM CAPSULES USP - 7.5 MG AND 22.5 MG1 ML AND 2 ML VIALS	071457	6/22/2012	NOVEL LABORATORIES INC

ZOLPIDEM TARTRATE TABLETS USP - 5 MG AND 10 MG	077388	7/30/12	CIPLA LIMITED

Table 6: Drug Products Containing Schedule II Controlled Substances Discontinued between January 2012 and December 2012

DRUG PRODUCT	NDA/ ANDA#	DATE OF DISCONTINUATION	SPONSOR
HYDROCODONE BITATRATE AND ACETAMINOPHEN ORAL SOLUTION, 7.5 MG/500 MG PER 15 ML	040366	7/7/12	NESHER PHARMACEUTICALS
VICODIN TABLETS, 5 MG/500 MG	088058	12/7/12	ABBVIE INC
VICODIN ES, 7.5 MG/750 MG	089736	12/7/12	ABBVIE INC
VICODIN HP, 10 MG/660 MG	040117	12/7/12	ABBVIE INC
ALPRAZOLAM EXTENDED-RELEASE TABLETS USP, 0.5 MG, 1 MG, 2 MG AND 3	077777	3/31/12	SANDOZ INC
ALPRAZOLAM EXTENDED-RELEASE TABLETS USP, 0.5 MG, 1 MG, 2 MG AND 3 MG	078442	7/26/12	VINTAGE PHARMACEUTICALS
DEXTROAMPHETAMINE SULFATE TABLETS, 5 MG	040365	11/19/12	NESHER PHARMACEUTICAL INC
DEXTROAMPHETAMINE SULFATE TABLETS, 10 MG	040367	11/19/12	NESHER PHARMACEUTICAL INC
DIAZEPAM INJECTION USP, 5 MG/ML	071584	5/9/12	HOSPIRA
HYDROMORPHONE HYDROCHLORIDE TABLETS USP, 2 MG, 4 MG AND 8 MG	077311	7/712	NESHER PHARMACEUTICAL S LLC
LORAZEPAM INJECTION USP, 2 MG/ML AND 4 MG/ML; 10 ML PER VIAL	077076	7/7/12	BEDFORD LABORATORIES
LORAZEPAM INJECTION USP, 2 MG/ML AND 4 MG/ML; 10 ML PER VIAL	074300	6/27/12	HOSPIRA INC
ZOLPIDEM TARTRATE TABLETS, 5 MG AND 10 MG	078016	10/27/12	MYLAN PHARMACEUTICALS