FY 2015 CDER INSPECTION OBSERVATIONS and WARNING LETTER DATA

In this report I cover both inspection observations and warning letter data for CDER. This supplements the data provided by FDA for the FY2015 enforcement metric addressed in an *earlier blog entry* and takes a deeper dive. The analysis compares results from the most recent fiscal year, 2015, with results from fiscal years 2013 and 2014. Data are sourced from the FDA website though often presented in a different manner. First we start with the *inspection observations* and determine which are the most common with some potential reasons for any obvious changes in 2015 over previous years. Then we move onto CDER GMP warning letters from the same time period and look at product category, geography, and trends in deficiencies that are cited. Appendices 1 – 3 provide listing and links to the warning letters for each of the fiscal years.

OVERALL CONCLUSIONS:

1. The CDER inspection observations did not change significantly between FY 2013 and FY2015, even though there are some slight increases in the frequency of some observations. These slight changes may represent the increased focus on compounding pharmacies and outsourcing facilities though data are not available to be sure about this. Remember that these data from FDA do not include all 483 observations, only those prepared within the Turbo EIR system.
2. Drug GMP warning letters issued to compounding pharmacies increased dramatically from FY2013 to FY2014 and 2015. This represents an unusual enforcement focus on a single segment of the drug industry. FDA's legal authority over these entities was clarified in the *Compounding Quality Act*, part of the Drug Quality and Safety Act signed into law in November of 2013 and explains the apparent explosion of enforcement action. FDA ORA *statistics* show that approximately 3% of inspections result in warning letters, but for compounding pharmacies the value is close to 40% according to *Lachman Consultants*. The number of warning letters issued to non-compounding pharmacy sites in the US decreased dramatically during the period. The number of warning letters issued to sites outside the US have also decreased since FY2013. Enforcement focus seems to be sharply focused on compounding pharmacies at the possible expense of both US and OUS pharma sites. (See Tables 2 and 3, Figures 3,4, and 5)
3. Between FY 2013 and 2015, many of the warning letters issued regarding sites located outside the US identified deficiencies in data integrity / data management. Percentages range between 40% and 81% increasing each year even though the number of OUS inspections decreased. If a warning letter addressed multiple sites it was counted only once so in reality the % of sites is understated. During this time, only 1 of the warning letters issued to non-compounding pharmacy sites in the US included data integrity deficiencies. This may be because there were so few US sites, other than compounding pharmacies, inspected during this time. Compounding pharmacies were excluded from the calculation. (See Table 4 and Figure 6)

INSPECTION OBSERVATIONS:

Here we go. The following data are based on inspections generated using the FDA Turbo-EIR system. Data from inspections of API manufacturers and forms 483 generated outside the system are not included. Data in the table 1 is collated based on data from the FDA web site

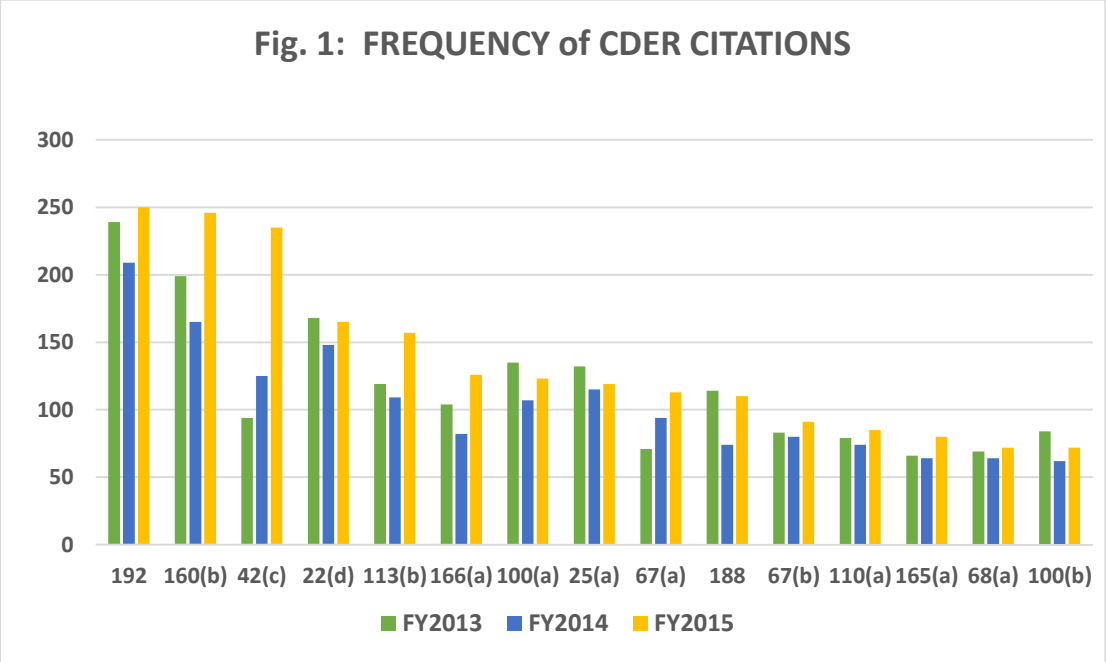
with one difference. For example, the citation 21 CFR 211.192 is actually divided into several line items throughout the FDA tables, I've consolidated them into a single line item. The same change has been made for each of the line items. Thus, when the numbers are consolidated it is obvious that problems with the topic of 'Production Record Review' and 'investigation of any unexplained discrepancy' are at the top of the list. As a result, 211.192 moves from third on the FDA list this year and in 2014 to first on the one below when all subsets are consolidated. In FY2013 FDA's tabulation lists 211.192 as second, but again, if all subsets are consolidated it becomes first. Table 1 shows only the most frequent group of inspection observations, the FDA tabulation shows all.

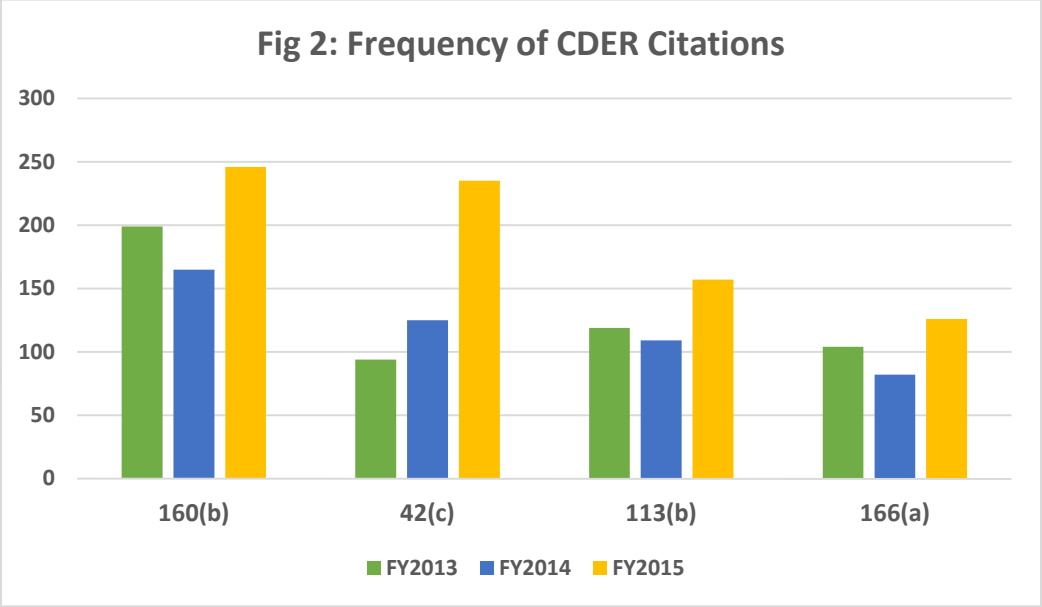
TABLE 1: Inspection Observations

CITATION	SHORT DESCRIPTION	2015	2014	2013
211.192	Production record review, investigations of discrepancies	250	209	239
211.160(b)	Development of scientifically sound specifications	246	165	199
211.42(c)	Requirement for adequate facilities to prevent contamination or mix-ups	235	125	94
211.22(d)	Quality unit responsibilities should be in writing and should be followed	165	148	168
211.113(b)	Validation of aseptic processes including sterilization	157	109	119
211.166(a)	Expiration dating should be supported by appropriate studies	126	82	104
211.100(a)	Written procedures shall describe production and process controls	123	107	135
211.25(a)	Staff shall have training, education and experience to perform their jobs	119	115	132
211.67(a)	Equipment shall be cleaned and maintained	113	94	71
211.188	Batch production records	110	74	114
211.67(b)	Procedures shall describe cleaning and maintenance of equipment	91	80	83
211.110(a)	Processes shall be validated	85	74	79
211.165(a)	Specifications shall be established for drug product	80	64	66
211.68(a)	Automatic equipment including computers shall be routinely calibrated and inspected	72	64	69
211.100(b)	Activities shall be documented at the time of performance	72	62	84

Figure 1 below shows the above group of inspection observations graphed over the three fiscal years 2013 – 2015. While there is some variation from year to year, the frequency with which specific regulations are identified remains fairly constant. Figure 2 shows additional detail of several of the areas where the frequency of the observation was higher in FY2015 than in the two previous years. This change could be due to the specific forms 483 that were generated

within the Turbo-EIR system. Alternatively, it's possible that they are due to FDA's intense focus on compounding pharmacy and outsourcing facility inspections. Many of these facilities have inspection observations in these four areas: the absence of scientifically sound specifications; lack of appropriately segregated facility areas to prevent contamination; lack of validation of aseptic processes including sterilization and expiry dating that is not supported by stability data. Impossible to know the real reason.





In conclusion, there is little change in the overall frequency of inspection observations, as characterized by the regulation cited, between FY2013 and 2015. The most frequent observations cite 211.192 (investigations), 211.160(b) (scientifically sound specifications) and 211.42(c) (validation of aseptic processes including sterilization). Where increases in specific observations are noted in Figure 2, it may be due to FDAs focus on inspections of compounding pharmacies and outsourcing facilities for which these are frequent observations. Data are not available to be sure about this possible conclusion.

DRUG GMP WARNING LETTERS

We look at the drug GMP warning letters in fiscal years 2013 through 2015. Appendices 1 – 3 provide tabulations of warning letters from each of the three years that identify product type covered in the letter, the issuing office, number of deficiencies identified, and the country in which the sites in question are located. Links are provided to each of the warning letters in these tables.

Table 2 shows that the number and percent of warning letters issued to compounding pharmacies increased dramatically between FY2013 and FY2015. This represents an unusual enforcement focus on a single segment of the pharmaceutical industry. FDA's legal authority over these entities was clarified in the DQSA legislation, signed in November of 2013 and explains the apparent explosion of enforcement action. Most of the compounding pharmacies who received these warning letters manufactured sterile injectable products. When removing compounding pharmacies from consideration, Table 2 also shows a dramatic drop in official enforcement actions against pharmaceutical firms in the US and a continued focus on sites outside the US. The numbers and percentage, however have decreased since FY2013. This is perhaps due to the focus on the domestic compounding pharmacy industry.

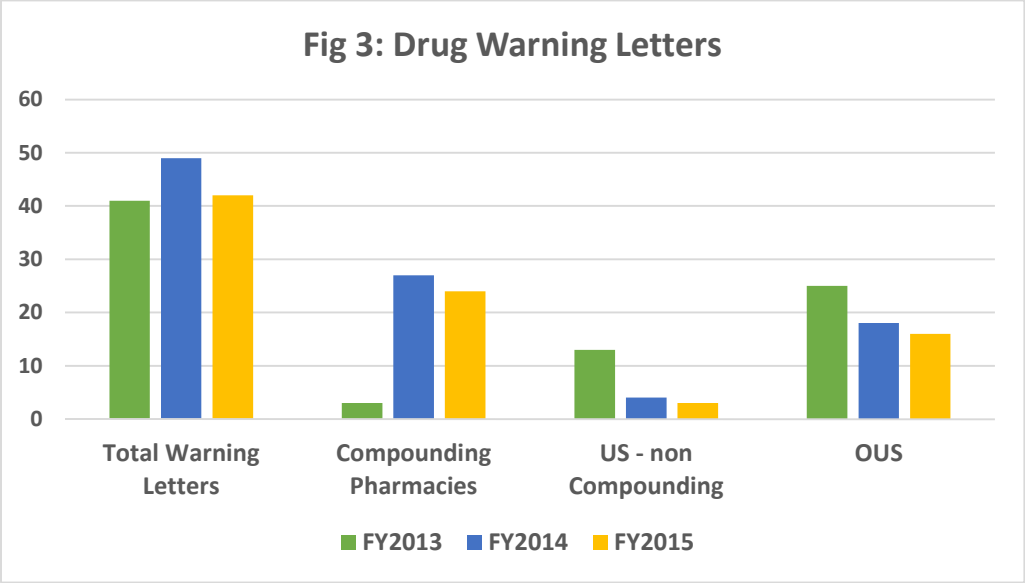
The involvement of API sites in warning letters increased since FY2013 have almost doubled. The number of non-compounding drug product sites has decreased by over half, again likely due to the FDAs focus on compounding pharmacies and outsourcing facilities. As we watch the percentage of warning letters issued to compounding pharmacies those issued both inside the US and outside the US to pharmaceutical manufacturers has diminished. This seems to represent FDA's allocation of their limited inspection resources. Figure 3 shows the high level data presented in Table 2. Figure 4 shows data regarding type of manufacture associated with warning letters not including compounding pharmacies. The focus on API sites has increased and the number of drug product sites has diminished over the time period.

Table 2: DRUG GMP Warning Letters

	FY2013	FY2014	FY 2015
TOTAL	**41***	**49****	**42**
Compounding pharmacies	**3** (7%)	**27** (55%)	**24** (57%)
US (non-compounders)	**13** (32%)	**4** (8%)	**3** (7%)
OUS	**25** (61%)	**18** (37%)	**16** (38%)
API sites	**5**	**8**	**9**

Drug Product (non-compounders)	**29**	**12**	**9**
API and drug product	**3**	**2**	**1**

*Includes one repackager not counted as either API or drug product
**Includes one warning letter regarding combination products, considered drug product



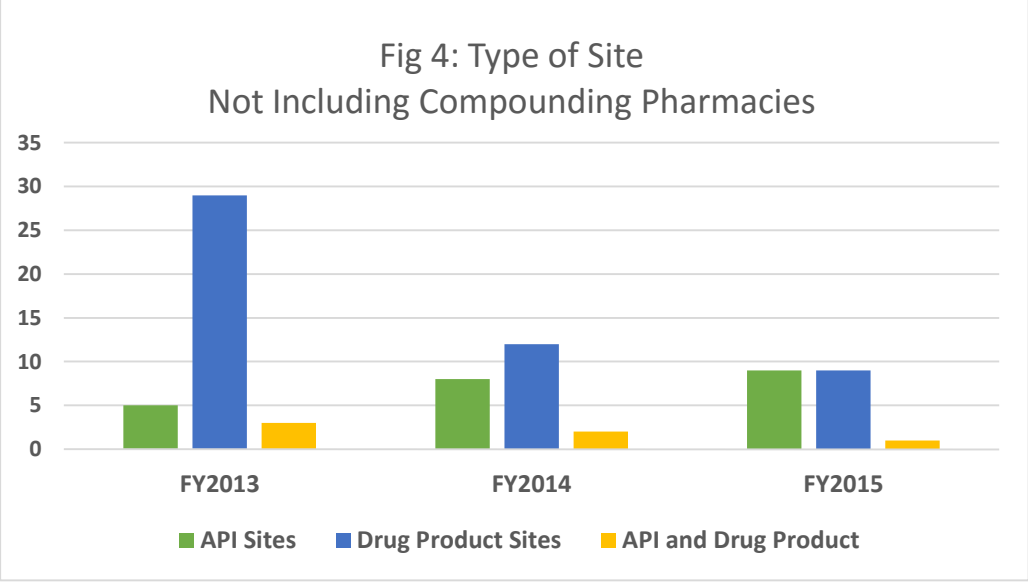
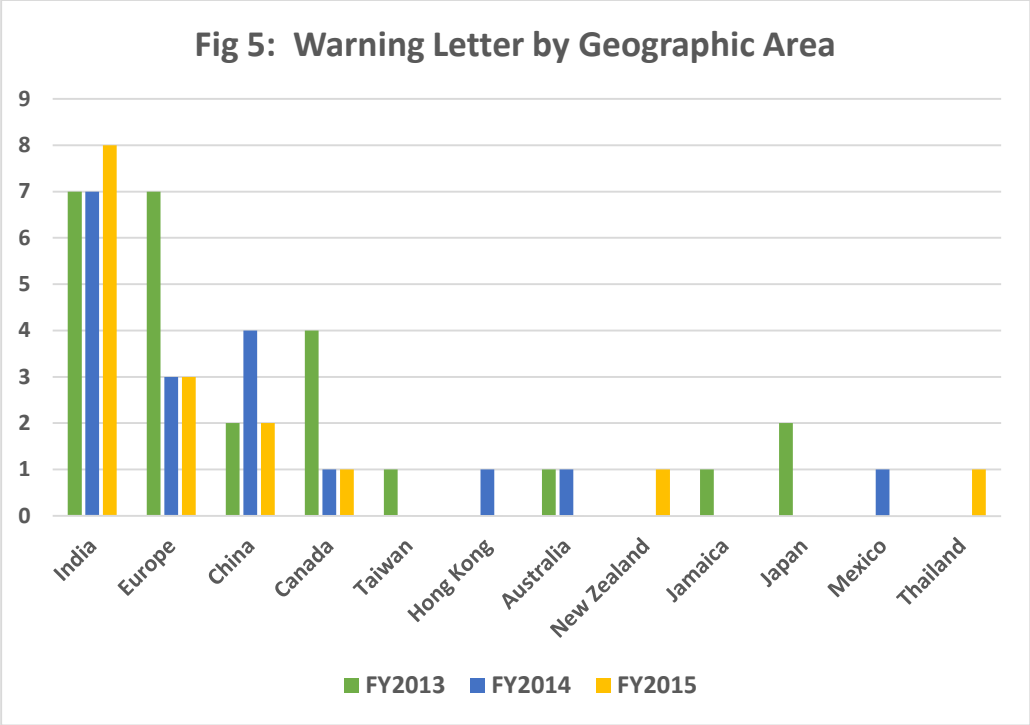


Table 3 shows the geographic distribution of warning letters issued outside the US. European countries are counted together since only in one year, FY2013, did any of the countries received more than 1 warning letter each. European area countries included over the three years include: Ireland, Spain, Czech Republic, Italy, Portugal, Denmark, Austria, Netherlands and Germany. The decrease in warning letters issued regarding sites in Europe may represent an 'unofficial' reliance on EMA inspections of sites located in this area even in the absence of an official mutual recognition agreement (MRA). Outside of the European area, India received the highest number of warning letters issued to a single country over the three-year time period. China received the next highest number of warning letters. Over this time, the inspections in China have been limited by the number of visas issued to FDA investigators. Thus, one should not assume the industry in India has more problems than the industry in China. For those who like graphs rather than tables (like me!) Figure 5 shows the same information.

TABLE 3. Drug GMP Warning Letters Issued Regarding Sites Outside the US

Country / Geography	FY2013	FY2014	FY2015	TOTAL
India	7	7	8	22
Europe	7	3	3	13
China	2	4	2	8
Canada	4	1	1	6
Taiwan	1			1
Hong Kong		1		1
Australia	1	1		2
New Zealand			1	1
Jamaica	1			1
Japan	2			2
Mexico		1		1
Thailand			1	1

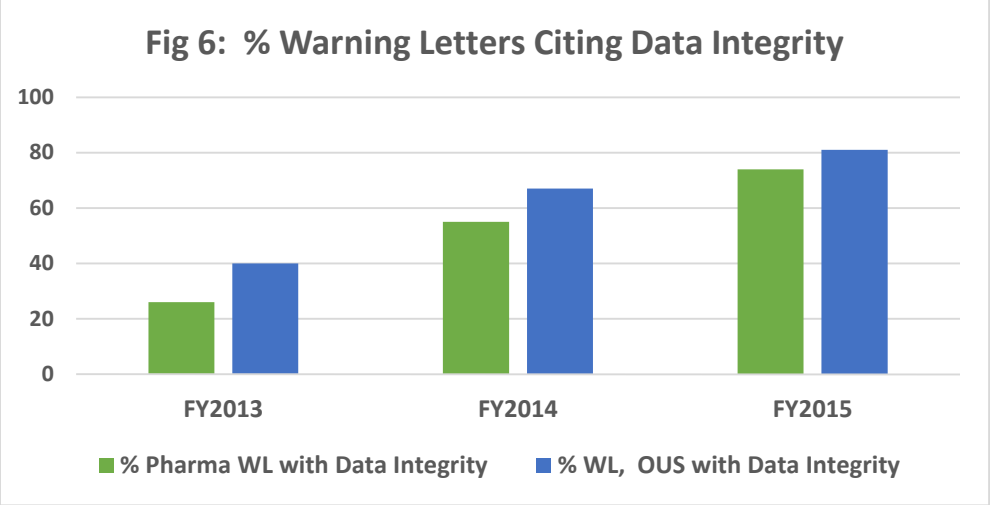


DATA INTEGRITY DEFIIENCIES IN WARING LETTERS

Table 4 shows the number of warning letters issued both inside and outside the US that included references to data integrity. This group and analysis excludes those warning letters issued to compounding pharmacies. Note that in Table 1, earlier in this document, no observations were cited against 21 CFR 11. Data integrity deficiencies, including those cited in warning letters, identify the predicate rule(s) to which firms did not adhere. Note that even though the total number of warning letters decreased during the time period, the percent that addressed data integrity increased. Figure 6 provides a graphic representation of the data.

TABLE 4: Data Integrity Deficiencies in Warning Letters

	FY2013	FY2014	FY2015
Total WLs in the group	**38**	**22**	**19**
US Sites with data integrity	**0 of 13** (0%)	**0 of 4** (0%)	**1 of 3** (33%)
OUS Sites with data integrity	**10 of 25** (40%)	**12 of 18** (67%)	**13 of 16** (81%)
TOTALNUMBER of WARNING LETTERS CITING DATA INTEGRITY	**10** (26%)	**12** (55%)	**14** (74%)



Most data integrity deficiencies addressed focus on the lack of controls over laboratory instrument associated computers / software or failure to contemporaneously record data. The warning letter issued to *Sun Pharmaceuticals* in early FY2016 (deficiency #6) focuses on **manufacturing instrumentation associated software and computer systems**. While related deficiencies have occasionally been identified in past warning letters, the clarity of focus in this deficiency may represent an area that inspectors will take in moving forward. Watch for more of this in FY2016 as FDA likely expands their scope to include more manufacturing floor computer systems.

Several of the warning letters from FY2015 included **requirements that approached consent decree like requirements**. Examples of requirements may be found in the warning letters issued to: Micro Labs Limited, Apotex Research Private Limited, Hospira Spa, Yunnan Hande Bio-Tech Ltd, and Cadila Healthcare Limited. Text for these requirements may be found in an *attachment* to a *previous blog*.

The **interval between inspection and warning letter issuance has generally increased significantly** as 2015 progressed with earlier warning letters issued 6-9 months after the inspection. Later in the year this was well over a year between the inspection and warning letter. Reference is made to a table on page 2 in a previous *blog entry*. In at least several cases, FDA acknowledged that firms brought in third party firms to assist in remediation. It suggests that even with third party assistance, some of the firms were not making adequate progress.

For those who want a deeper dive into the area, please see the related Linked-In article *HERE*.

If you have questions or would like additional detail or assistance with either GMP auditing or your GMP Intelligence program, please contact me at bwunger123@gmail.com

APPENDIX 1

DRUG GMP WARNING LETTERS, FY2013

Product Type	Issue Date	Company Name	Issuing Office	Number of Deficiencies	Country
repackager	9-Oct-12	Stat Rx US	Atlanta	3	USA
Drug product	23-Oct-12	International Laboratories Ltd.	Center	5	Canada
Drug Product	14-Nov-12	Shanghai Huhui Daily Use Chemical Products Co., Ltd	Center	6	China
Drug Product	12-Dec-12	Novo Nordisk A/S	Center	2	Denmark
Drug Product	17-Dec-2012	Hameln Pharmaceuticals GmbH	Center	3	Germany
Drug Product	17-Dec-12	Taiwan Three Mast Pharmaceutical Co Ltd.	Center	5	Taiwan
Drug Product	10-Jan-13	Physicians Total Care, Inc.	Dallas	5	USA
Drug Product	29-Jan-13	Sovereign Pharmaceuticals, LLC	Dallas	2	USA
Drug Product	29-Jan-13	P.A. Benjamin Manufacturing Co., Ltd.	Center	6	Jamaica
Drug Product	20-Feb-13	Jubilant HollisterStier General Partnership	Center	3	Canada
API	19-Feb-13	Abbey Color Inc	Philadelphia	3	USA
Drug product	14-Feb-13	Laclede Inc	Los Angeles	3	USA
Drug product	21-Feb-13	Apotex Inc	Center	5	Canada
compounding pharmacy	7-Mar-13	Medi-Fare Drug and Home Health Center	Atlanta	6	USA
Drug Products	18-Mar-13	Keystone Laboratories Inc	New Orleans	5	USA
API	22-Mar-13	Alexion Pharmaceuticals	New England	2	USA
API	22-Mar-13	Asada Milling Co., Ltd	Center	6	Japan
Drug Product	22-Mar-13	Peking Medicine Manufactory	Center	5	China
Drug Product	27-Mar-13	Wyeth Lederle (Pfizer)	Center	2	Italy
Drug Product	1-Apr-13	Kanebo Cosmetics Inc	Center	4	Japan
Drug Product	25-Apr-13	CMI Cosmetic Manufacturers	Center	3	Canada
Drug Product	26-Apr-13	V-SAB Medical Labs	Atlanta	4	USA
API and Drug Product	6-May-13	Boehringer Ingelheim	Center	4	Germany
Compounding Pharmacy	15-May-13	Custom Compounding Centers	Los Angeles	5	USA
Drug Product	17-May-13	Contract Pharmaceutical Services	Center	3	Australia

Drug Product	28-May-13	*Ebewe Pharma (Novartis)*	Center	2	Austria
API and Drug Product	28-May-13	*RPG Life Sciences Limited*	Center	7	India
Drug Product	31-May-13	*Baxter Healthcare*	Atlanta	5	USA
API	1-Jul-13	*Fresenius Kabi Oncology Limited*	Center	4	India
Drug Product	2-Jul-13	*Cispharma Inc.*	New Jersey	4	USA
Drug Product	18-Jul-13	*Wockhardt Limited*	Center	6	India
API and Drug Product	3-Jul-13	*Aarti Drug Limited*	Center	4	India
API	2-Aug-13	*Posh Chemicals Private Limited*	Center	3	India
Drug Product	9-Aug-13	*Promed Exports Private Limited*	Center	2	India
Drug Product	16-Aug-13	*Fenwal, a Fresenius Kabi Company*	San Juan	4	USA (PR)
compounding pharmacy	21-Aug-13	*Stewart Compounding Pharmacy*	Atlanta	6	USA
Drug Product	22-Aug-13	*Jabones Pardo S.A.*	Center	5	Spain
Drug Product	29-Aug-13	Sanquin Plasma Medical Products	Center	21	Netherlands
Drug Product	30-Aug-13	*Lloyd Inc of Iowa*	Kansas City	7	USA
Drug Product	9-Sep-13	*Agila Specialties Private Limited*	Center	7	India
Drug Product	4-Sep-13	*Allergy Laboratories Inc*	Center	5	USA

APPENDIX 2

DRUG GMP WARNING LETTERS, FY 2014

Product Type	Issue Date	Company Name	Issuing Office	Number of Deficiencies	Country
Drug Product	25-Nov-13	*Wockhardt Limited*	Center	4	India
Drug Product	27-Nov-13	*Jubilant HollisterStier, LLC*	Seattle	2	USA
Drug Product	2-Dec-13	*Amerideerm Laboratories, Ltd.*	New Jersey	6	USA
Compounding Pharmacy	14-Jan-14	*Avella of Deer Valley*	LA District	3	USA
Compounding Pharmacy	14-Jan-14	*Triangle Compounding*	Atlanta District	6	USA
Compounding Pharmacy	15-Jan-14	*Medaus Inc*	New Orleans	6	USA
Combination Product	27-Jan-14	*Amgen Inc.*	Los Angeles	3	USA
API	31-Jan-14	*CBSCHEM Limited*	Center	6	Hong Kong
Drug Product	6-Feb-14	*Usv Limited*	Center	2	India
Compounding Pharmacy	14-Feb-14	*Nora Apothecary Pharmacy*	Detroit	5	USA
Compounding Pharmacy	18-Feb-14	*Olympia Pharmacy*	Florida	6	USA
Compounding Pharmacy	19-Feb-14	*Pallimed Solutions Inc*	New England	7	USA
Compounding Pharmacy	21-Feb-14	*Wedgewood Village Pharmacy*	New Jersey	8	USA
API	27-Feb-14	*Canton Laboratories Private*	Center	4	India
Compounding Pharmacy	28-Feb-14	*Village Fertility Pharmacy*	New England	4	USA
Compounding Pharmacy	28-Feb-14	*Total Pharmacy Services Inc*	New Orleans	6	USA
API	6-Mar	*Smuthri Organics Limited*	Center	3	India
Compounding Pharmacy	7-Mar-14	*Pentec Health*	Philadelphia	2	USA
Drug Product	18-Mar-14	*SmithKline Beecham*	Center	3	Ireland
API/drug product	4/11/2014	*SANUM-Kehlbeck GmbH & Co KG*	Center	6	Germany
Drug product	16-Apr-14	*Instituto Bioclon*	Center	15	Mexico
Drug Product	21-Apr-14	*Greer Laboratories*	Center	8	USA

Compounding Pharmacy	30-Apr-14	Blue Ridge Pharmacy	Atlanta	8	USA
Compounding Pharmacy	2-May-14	Grandpa's Compounding Pharmacy	San Francisco	5	USA
Compounding Pharmacy	2-May-14	Brookfield Prescription Center	Minneapolis	7	USA
API and Drug Product	7-May-14	Sun Pharmaceuticals	Center	5	India
Compounding Pharmacy	9-May-14	Nature's Pharmacy and Compounding Center	Atlanta	7	USA
Compounding Pharmacy	6-Jun-14	Lee and Company	Dallas	3	USA
API	10-Jun-14	Tianjin Zhongan Pharmaceutical Co Ltd	Center	3	China
Drug product	12-Jun-14	ID Biomedical Corp (GSK subsidiary)	Center	5	Canada
API	16-Jun-14	Apotex Pharmachem India Pvt Ltd	Center	4	India
Compounding Pharmacy	23-Jun-14	Pharmacy Creations	New Jersey	8	USA
Compounding Pharmacy	22-Jan-14	Home Intensive Care Pharmacy	Dallas	5	USA
Compounding Pharmacy	27-May-14	Oakdell Pharmacy Inc	Dallas	6	USA
Compounding Pharmacy	14-Jul-14	RC Compounding Services	Cincinnati	1	USA
Compounding Pharmacy	18-Jul-14	PharMEDium Services LLC	Chicago	12	USA
Compounding Pharmacy	7-Jul-14	JCB Labs LLC	Kansas City	1	USA
API	7-Jul-14	Trifarma S.p.A.	Center	3	Italy
API	9-Jul-14	Zhejiang Jiuzhou PHarmaceutical Co Ltd	Center	4	China
Drug Product	8-Jul-14	Marck Bioscience Ltd.	Center	6	India
Compounding Pharmacy, animal drug	14-Aug-14	Wickliffe Pharmacy	Cincinnati	1	USA
Compounding Pharmacy	15-Aug-14	Zion Rx Formulations Services LLC dba Rx Formulations Serv.	Los Angeles	6	USA
Compounding Pharmacy	12-Aug-14	The Compounding Shop	Florida District	6	USA
Compounding Pharmacy	4-Sep-14	John W Hollis	New Orleans District Office	7	USA

Compounding Pharmacy	6/27/2014	*Clinical Specialties Compounding Pharmacy*	Atlanta District	1	USA
Drug Product	9/26/2014	*Hospira, Mugrave Australia*	Center	3	Australia
Drug Product	9/19/2014	*China Resources Sanjiu Medical and Pharmaceutical Company*	Center	4	China
Compounding Pharmacy	9/24/2014	*Beacon Hill Medical Pharmacy*	Detroit District	7	USA
API	9/29/2014	*Beijing Shunxin Medical and BioTechnical*	Center	1	China

APPENDIX 3

DRUG GMP WARNING LETTERS, FY2015

PRODUCT TYPE	DATE	NAME	DISTRICT	DEFICIENCIES	LOCATION
API	10/15/2014	Sharp Global Limited	PHS/Center	3	India
API	10/15/2014	Cadila Pharmaceuticals Limited	PHS/Center	3	India
Drug product	10/21/2014	Hikma Farmaceutica	PHS/Center	2	Portugal
Compounding Pharmacy	10/23/2014	RX South DBA RX3 Compounding Pharmacy	Baltimore District Office	4	USA
Compounding Pharmacy	10/24/2018	Pharmagen Laboratories	New England	4	USA
Compounding Pharmacy	10/29/2018	Eastern Pharmacy Inc	Florida District Office	1	USA
Compounding Pharmacy	11/11/2018	Wells Pharmacy Network LLC	Florida District Office	6	USA
Cell Therapy (drug product)	11/20/2014	New Hope Fertility Center	New York District	6	USA
Compounding Pharmacy	12/9/2014	Delta Pharma Inc	New Orleans	4	USA
API and dosage form	12/19/2014	Novacyl Wuxi Pharmaceutical Co. Ltd	PHS/Center	4	China
Drug product	1/9/2015	Micro Labs Limited	PHS/Center	4	India
compounding Pharmacy	1/21/2015	Cantrell Drug Company	Dallas District	4	USA
compounding Pharmacy	1/27/2015	Oregon Compounding Centers	Seattle District	6	USA
Drug Product	1/30/2015	Apotex Research Private Ltd	PHS/Center	4	India
compounding Pharmacy	2/13/2015	Pine Pharmacacy and Home Care Products Inc	New York District	5	USA
API	2/27/2015	Novacyl Ltd. (Thailand)	PHS/Center	3	Thailand
compounding Pharmacy	3/27/2015	Kings Park Slope Inc.	New York District	3	USA
compounding Pharmacy	3/27/2015	Alexander Infusion LLC	New York District	6	USA

Drug product	3/31/2015	*Hospira Spa*	Center	4	Italy
Dosage Form, PADE + GMP	4/3/2015	Galena BioPharma Inc.	Seattle District	2	USA
API	4/6/2015	Yunnan Hande Bio-Tech Ltd	Center	3	China
compounding Pharmacy	4/8/2015	Region Care Inc.	Center	6	USA
compounding Pharmacy	4/14/2015	Leiter's Compounding	San Francisco	6	USA
compounding Pharmacy	4/21/2015	I.V. Specialty, Ltd	Dallas District	6	USA
compounding Pharmacy	4/27/2015	Premier Pharmacy Labs Inc.	Florida District	6	USA
compounding Pharmacy	4/27/2015	Absolute Pharmacy, LLC	Florida District	7	USA
compounding Pharmacy	4/29/2015	Vann Healtcare Services Inc	Cincinnati District	6	USA
compounding Pharmacy	5/14/2015	HHCS Pharmac Inc	Florida District	4	USA
API	5/27/2015	VUAB Pharma a.s.	Center	2	Czech Republic
compounding Pharmacy	6/4/2015	Green Hills Health and Wellness Pharmacy Inc.	New Orleans	5	USA
Finished pharmaceutical (medical gas)	6/8/2015	Transox Inc	Atlanta District	2	USA
compounding Pharmacy	6/17/2015	California Pharmacy and Compounding Center	LA District	5	USA
API	6/22/2015	Attix Pharmaceuticals	Center	1	Canada
compounding Pharmacy	6/25/2015	SCA Pharmaceuticals	Dallas District	3	USA
compounding Pharmacy	7/6/2015	KRS Global Biotechnology, Inc	Florida District	4	USA
API	7/23/2015	Sipra Labs Limited	Center	2	India
Drug product	8/16/2015	Mylan Laboratories Limited	Center	9	India
compounding Pharmacy	8/11/2015	Coram Healthcare Corp. of Indiana	Detroit District	3	USA
compounding Pharmacy	8/31/2015	Specialty Medicine Compounding Pharmacy, P.C.	Detroit District	8	USA

API	9/2/2015	Pan Drugs Ltd.	Center	3	India
dosage form	9/4/2015	Jaychem Industries, Ltd.	Center	4	NewZealand
API	9/28/2015	Unimark Remedies Ltd.	Center	4	India
compounding Pharmacy	9/29/2015	Hieber's Pharmacy	Philadelphia District	4	USA