FDA recently published *enforcement metrics for FY 2016*. This practice began with the publication of FY2009 data. The metrics provides a high-level overview of enforcement actions including: injunctions, seizures, warning letters and recalls conducted by all FDA Centers. This posting will look at the data from the enforcement metrics in two ways:

1. First, we will address the **data presented in the FY2016 slide deck**. These data represent all centers of the FDA: Center for Drug Evaluation and Research (CDER), Center for Biologic Evaluation and Research (CBER), Center for Devices and Radiologic Health (CDRH), Center for Veterinary medicine (CVM), Center for Food Safety and Nutrition (CFSAN) and Center for Tobacco Products (CTP).
2. Second, we've developed **additional graphs from data in FDA enforcement metrics** published between 2009 through 2016 that address only CDRH (devices) and CDER (drugs). We look at trends over the entire interval for a selected set of actions. Data from CBER, CFSAN, CVM and CTP are not included. CBER is not included because an overwhelming number of their enforcement actions are taken against blood and plasma entities. The figures in this section are *not* published in the FDA metrics although the data come from those metrics.

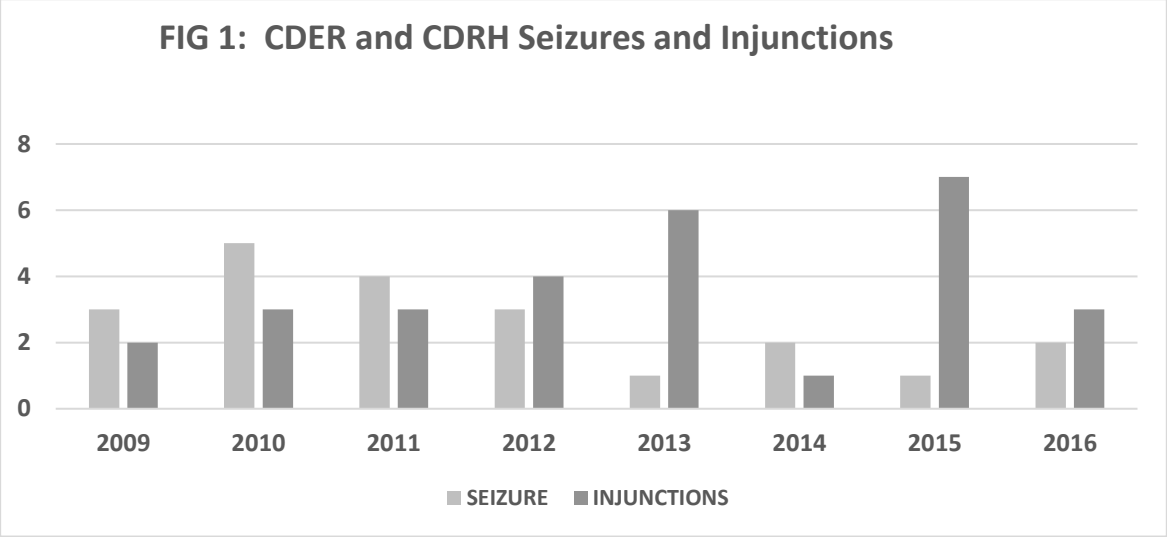
CONCLUSIONS based on FDA FY2016 Enforcement Metrics: Each conclusion references the slide number(s) in the *FDA deck*.

- Four (4) **product seizures** occurred in FY2016, up from one in FY2015 and down from a high of 15 in FY2011. The number of seizures decreased consistently since 2011 except for this past year. Two of the seizures were made at the request of CFSAN, and one each at the request of CDRH and CDER. (Slides 2 and 3).
- FDA **Injunctions** decreased from 21 in FY2015 to 17 in FY2016. CFSAN continues to be the most active Center here with 13 of the 17 injunctions associated with firms whose products they regulate. CDER was associated with 3 and CVM with 1. CDRH, CBER, CTP had none. (Slides 4 and 5)
- The total number of **warning letters** from all Centers decreased from 17232 in FY2015 to 14590 in FY2016. The Center for Tobacco products issued 96% of the warning letters this year, continuing to be the dominant player here. This year warning letters are distributed as follows: CTP (14032), CFSAN (253), CDER (151), CDRH (85), CVM (65), CDER (151), and CBER (4). *Note* that these include ALL warning letters, not just those issued for GMP deficiencies. (Slide 6 and 7)
- CDRH had the highest number of **total recall events** in FY2016, as they did last year, with 1183 followed by CFSAN (691), CBER (575), CDER (277) and CVM (121). CTP had no recalls for the year. This includes all classes of recalls. (Slide 8)
- CDRH had the highest number of **recalled products** in FY2016 with 2898. They were followed by CFSAN (2566), CDER (1550) CBER (781) and CVM (510). This includes all classes of recalls. (Slide 9)
- For all Center, and all Classes of Recalls, the number of **recalled products** dropped slightly to 8305 from 9178 in FY2015. The average number of recalled products over the six years covered in the figure is 8724, with a high of 9469 in 2012 and a low of 8044 in 2013. (slide 10)
- CFSAN led FY2016 in the number of **Class I recalled products** (1134), followed by CVM (272), CDRH (111), CDER (108) and CBER (1). (Slide 12)
- CDRH led FY2016 in the number of **Class II recalled products** (2671) followed by CDER (1272), CFSAN (1154), CBER (513), and CVM (222). (Slide 13)
- CFSAN led FY2016 in the number of **Class III recalled products** (278) followed by CBER (267), CDER (170), CDRH (116) and CVM (16). (Slide 14)

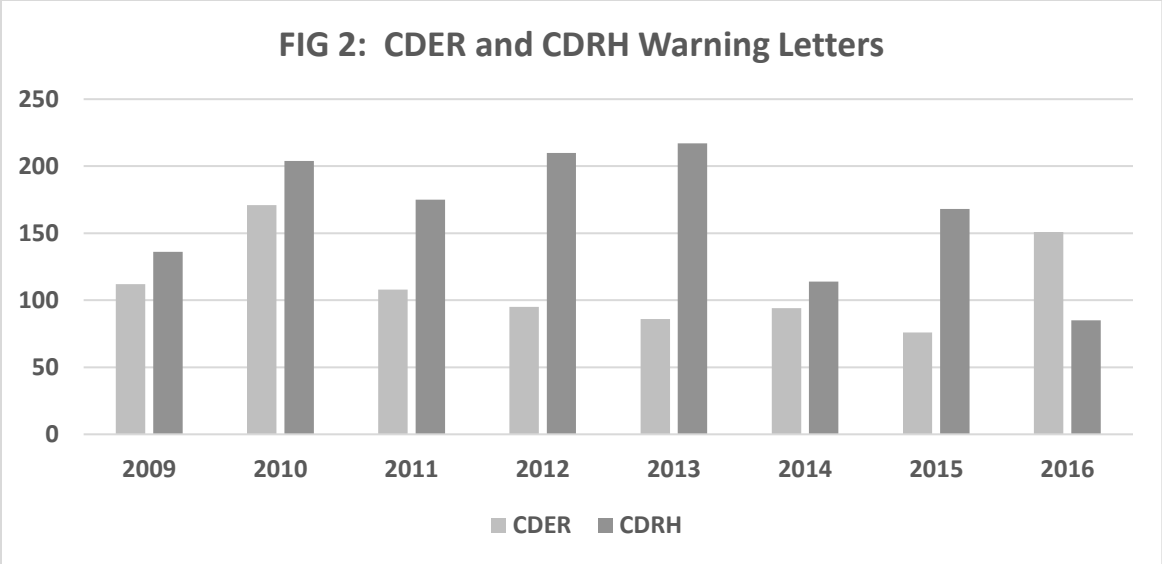
CONCLUSIONS based on FDA data from FY 2004 through FY2016 for CDER and CDRH.

Data used to construct the Figures below are taken directly from the *FDA slide decks* of enforcement actions from 2009 through 2016. The figures do not, however, appear in the FDA slide decks. All data are in fiscal years (FY).

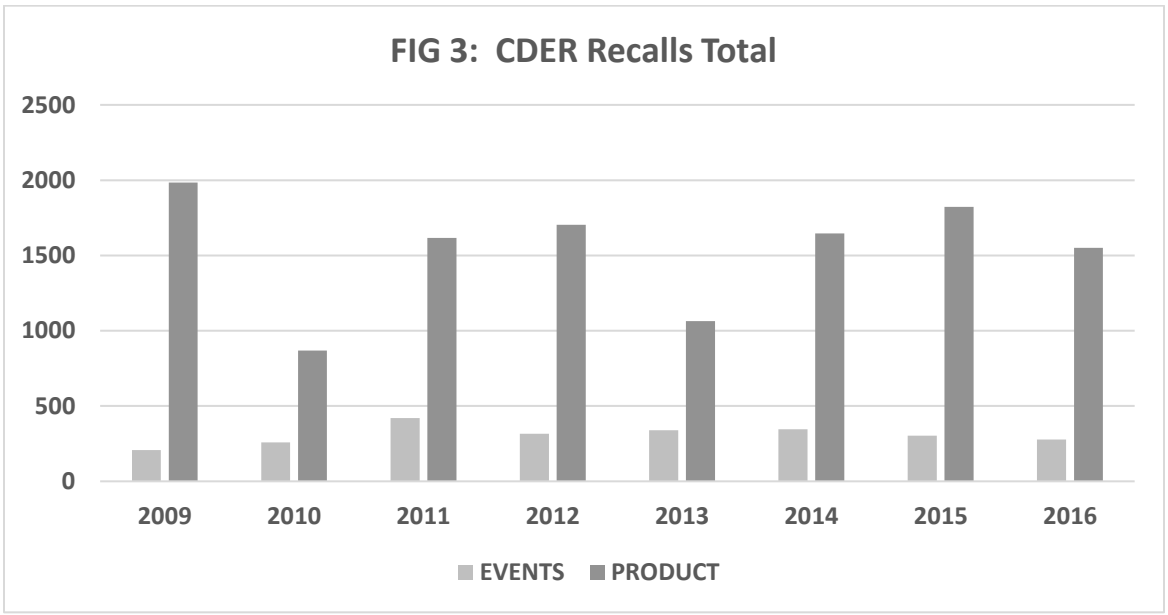
- **Figure 1** shows the combined number of product **seizures** associated with CDER and CDRH decreased between 2010 and 2013 and then varied between one and two each year through 2016. The number of seizures are low, less than or equal to five, and don't readily allow identification of trends. **Figure 1** also shows the combined number of **injunctions** associated with CDER and CDRH increased between 2009 and 2013, but decreased in 2014, rose to a new high in 2015 and then dropped again in 2016. Overall, the numbers have increased since 2009 with significant decreases in in 2014 and 2016 over the previous year. Like the number of seizures, these numbers are small and may simply represent normal variation.



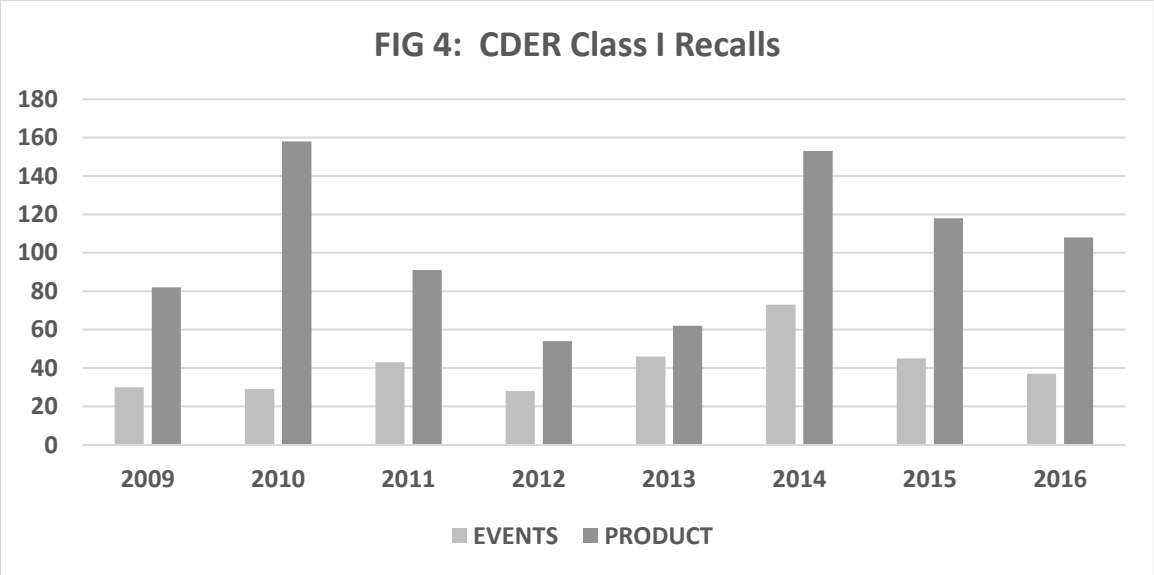
- Figure 2 shows **warning letters issued by CDER** decreased gradually from their peak in 2010 with a significant increase in 2016 that did not reach the number issued in 2010. **Warning letters issued by CDRH** increased slightly between 2010 thru 2013 (with a dip in 2011), followed by a dramatic decrease, in FY2014, increase in 2015 and another drop in 2016. The total, however, remain below the numbers issued in 2010 through 2013. Please note these are not exclusively GMP warning letters but include ALL warning letters issued by the specific Center.



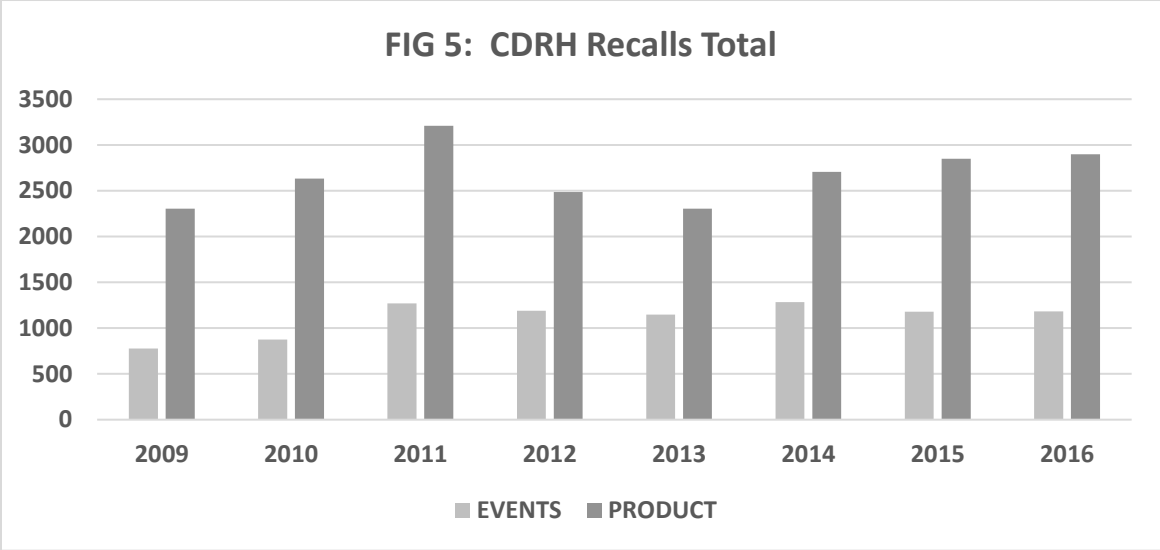
- **Figure 3** presents the **total CDER recalls events** and shows no obvious trend over the period 2009 – 2016. Recall events range from 207 to 419 with an average of 308 over the 8 years. The number of **recalled products** continues to outnumber the number of recall events. The number of recalled products has remained reasonably constant except for 2010 and 2013 where number were down by approximately 30%.



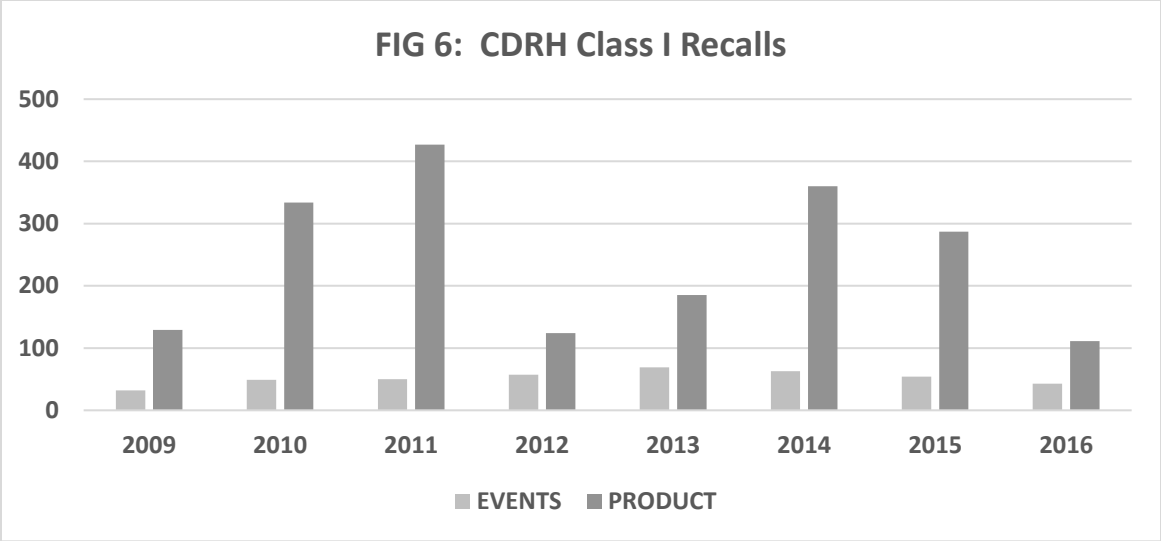
- **Figure 4** shows the number of **Class I CDER recall events** gradually increased from 2009 through 2014 and fell in 2015 and again in 2016. The number of **products subject to a Class I recall** in each year reached a high point in 2010, decreased in each of the next two years and then increased so that the number for 2014 was essentially the same as in 2010. In 2015 and 2016 the numbers of both recall events and recalled products decreased from 2014.



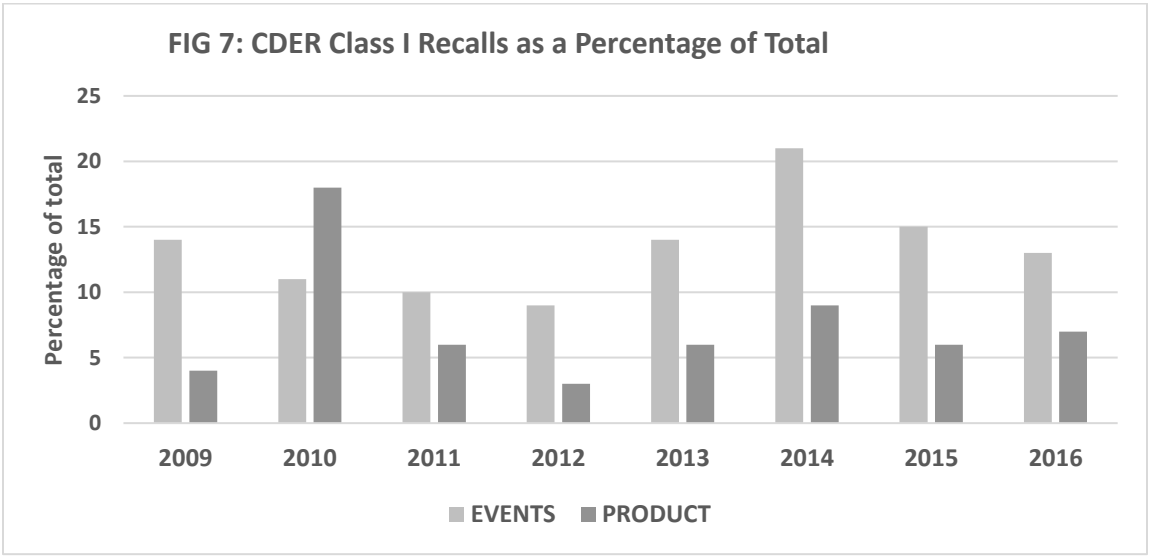
- **Figure 5** shows that **total CDRH recall events** increased from 2009 to 2010 and into 2011. They remained reasonably consistent from 2011 through 2016. The average number of events in the 8 years is 1,113 and range between 776 and 1283. The number of **CDRH recalled products** increased from 2009 through 2011, then decreased through 2013 only to increase again in 2014 through 2016. The average number of recalled products during the period is 2,675 with a range 2304 to 3211.



- Figure 6 shows the number of **CDRH Class I recall events** per year has consistently hovered at approximately 50. shows the number of **CDRH Class I products subject to recalls** increased from 2009 through 2011, decreased precipitously in 2012, increased again through 2014 and continues to measurably decrease in both 2015 and 2016.

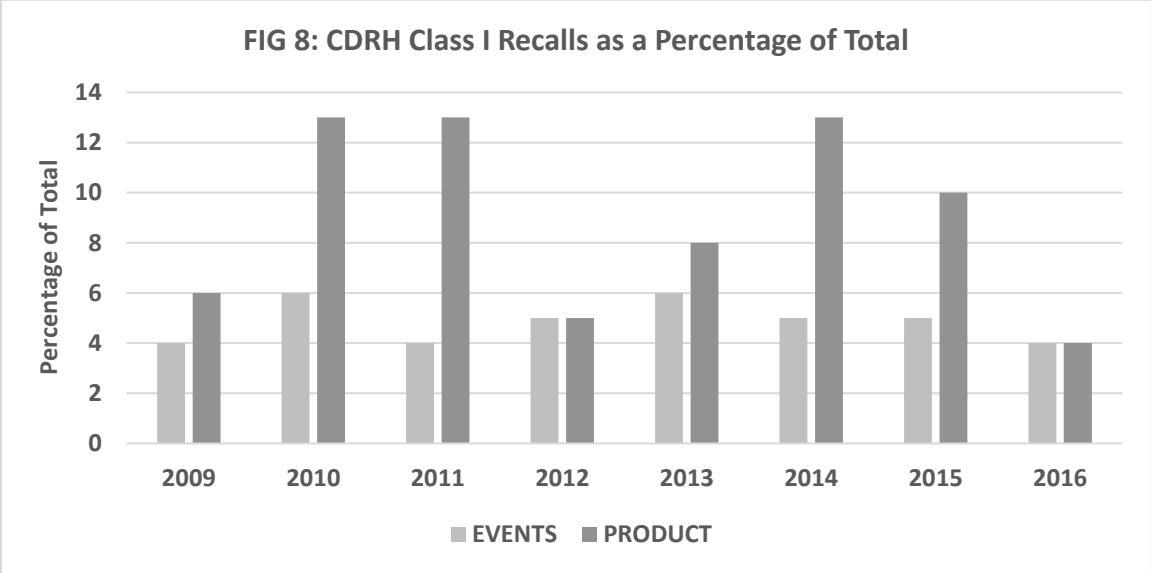


- The question often arises whether **Class I recalls as a percentage of total recalls** is increasing over time. When considering **CDER Class I recall events** as a percentage of the total CDER recall events, **Figure 7** shows that values from 2009 through 2013 varied between 9% and 14%. In 2014, the value increased significantly to 21% then fell in 2015 to 15% and again in 2016 to 13%. The number of **CDER Class I recalled products** as a percentage of the total decreased slightly between 2009 and 2012, increased until 2014 and then fell again in 2015 and 2016. This may simply represent normal variability given small numbers but it is something we will monitor in the future.



- The question often arises as to whether **Class I recalls as a percentage of total recalls** is increasing over time. When considering **CDRH Class I recall events** as a percentage of the total of CDRH **recall events**, **Figure 8** shows that values remain consistent between 4% and 6%. For CDRH Class I **recall products** as a percentage of total CDRH recalled products, the values between 2009 and 2011 increase then decrease by approximately half in 2012. From 2012 through 2014 they increase again to the levels of 2010 and 2011 but

then decrease in 2015 and again in 2016. This may simply represent normal variability given small numbers but it is something we will monitor in the future.



CONCLUSIONS:

It's always interesting to use the past as a roadmap to the future. This year it may be a bit more complicated with the new administration in the White House. They clearly intend to diminish regulations; not much has been said about enforcement actions. Time will tell. Until the new FDA Commission is in place and articulates strategy and tactics for the future, it will be a wait and see situation and we may continue as we did in 2016. Stay tuned, we will monitor this and let you know what we see and read.

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