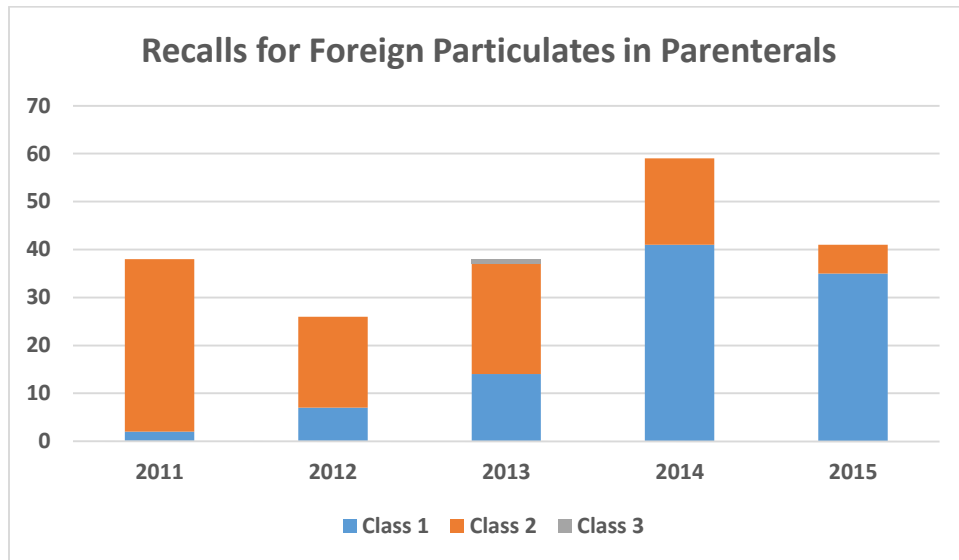
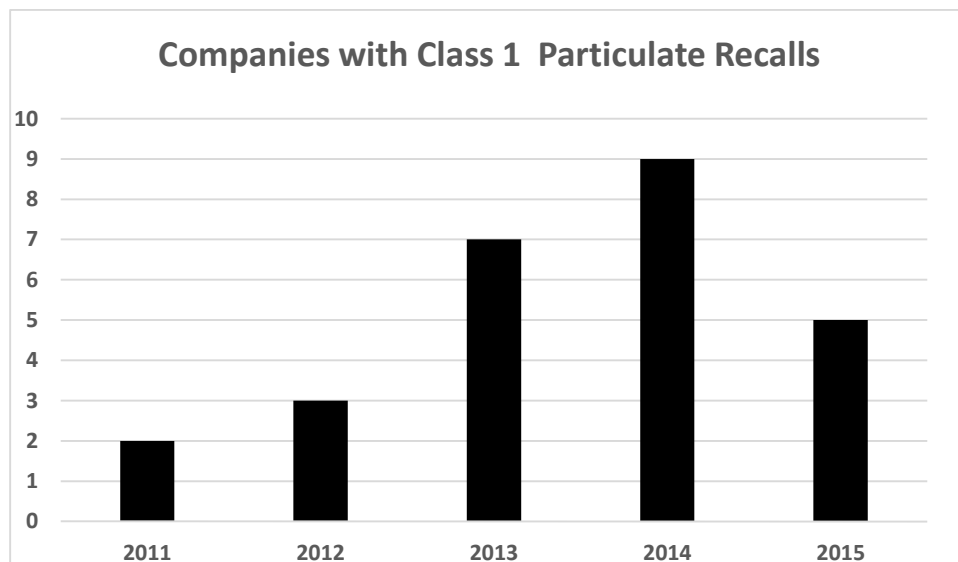


## PARENTERAL RECALLS FOR FOREIGN PARTICULATES:

Throughout calendar year 2015 we have followed the recalls of parenteral products based on the presence of foreign particulates. It seems that we have turned the corner here and such recalls, particularly those of the Class I category, are ever so slowly beginning to decrease. It's unclear whether this is due to changes in the FDA position on such potential recalls or whether industry is improving their ability to manufacture products without foreign particulates. The numbers would actually be lower in 2015 except for 14 recalls by a compounding pharmacy that used saline diluent that was itself the subject of a Class I recall. If we subtract the 14 recalls by the compounder, it would leave us with 21 Class I recalls, and 27 total recalls for the year. This total number approaches the value for 2012 even though the number of Class I recalls are higher than in 2012 where most of the recalls were Class II.



In another positive sign, the number of firms with Class I recalls in this area is lower than in both 2013 and 2014.



We began collecting data in 2011 and now have all data from the enforcement reports for 2015. All data come from the weekly FDA published enforcement reports, posted on their website. We will continue to monitor these recalls through 2016.