# Exhibit 9

# Inspection Observations

FDA's Office of Regulatory Affairs (ORA) is the lead office for all field activities, including inspections and enforcement. During an inspection, ORA investigators may observe conditions they deem to be objectionable. These observations, are listed on an FDA Form 483 when, in an investigator's judgment, the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA's requirements.

Spreadsheets summarizing the areas of regulation cited on FDA's system-generated 483s are available by fiscal year on the menu links on this page. These spreadsheets are not a comprehensive listing of all inspectional observations (/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspectional-observations-and-citations) but represent the area of regulation and the number of times it was cited as an observation on an Form FDA 483 during inspections conducted by FDA and its representatives. Inspectional observations reflect data pulled from FDA's electronic inspection tools. These tools are used to generate the Form FDA 483 when necessary. Not all Form FDA 483s are generated by these tools as some 483s are manually prepared. Observations have been broken out by Product or Program Area on separate tabs of the spreadsheet. The Product and Program Areas include the following:

- Biologics
- Drugs
- Devices
- Human Tissue for Transplantation
- Radiological Health
- Parts 1240 and 1250
- Foods (includes Dietary Supplements)
- Veterinary Medicine
- Bioresearch Monitoring
- Special Requirements
- Total number of inspections and 483s

For further information as well as an example of a standard citation, visit our Inspectional Observations: Citations (/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspectional-observations-and-citations) and Frequently Asked Questions (/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions) pages. Examples of recently issued 483s are available in ORA's Electronic Reading Room (/ora-foia-electronic-reading-room).

Questions regarding Inspection Observations may be directed by email to FDAInspectionsObservations@fda.hhs.gov (mailto:FDAInspectionsObservations@fda.hhs.gov?subject=Inspections Observations).

## Download Inspectional Observation Data Sets

- FY 2022 Excel File (/media/163420/download)
- FY 2021 Excel File (/media/153238/download)
- FY 2020 Excel File (/media/143942/download)
- FY 2019 Excel File (/media/132571/download)
- FY 2018 Excel File (/media/123311/download)
- FY 2017 Excel File (/media/109749/download)
- FY 2016 Excel File (/media/101615/download)
- FY 2015 Excel File (/media/95336/download)
- FY 2014 Excel File (/media/90525/download)
- FY 2013 Excel File (/media/87426/download)

- FY 2012 Excel File (/media/84715/download)
- FY 2011 Excel File (/media/84710/download)
- FY 2010 Excel File (/media/80684/download)
- FY 2009 Excel File (/media/80693/download)
- FY 2008 Excel File (/media/80699/download)
- FY 2007 Excel File (/media/80709/download)
- FY 2006 Excel File (/media/80720/download)