TCG Newsletter

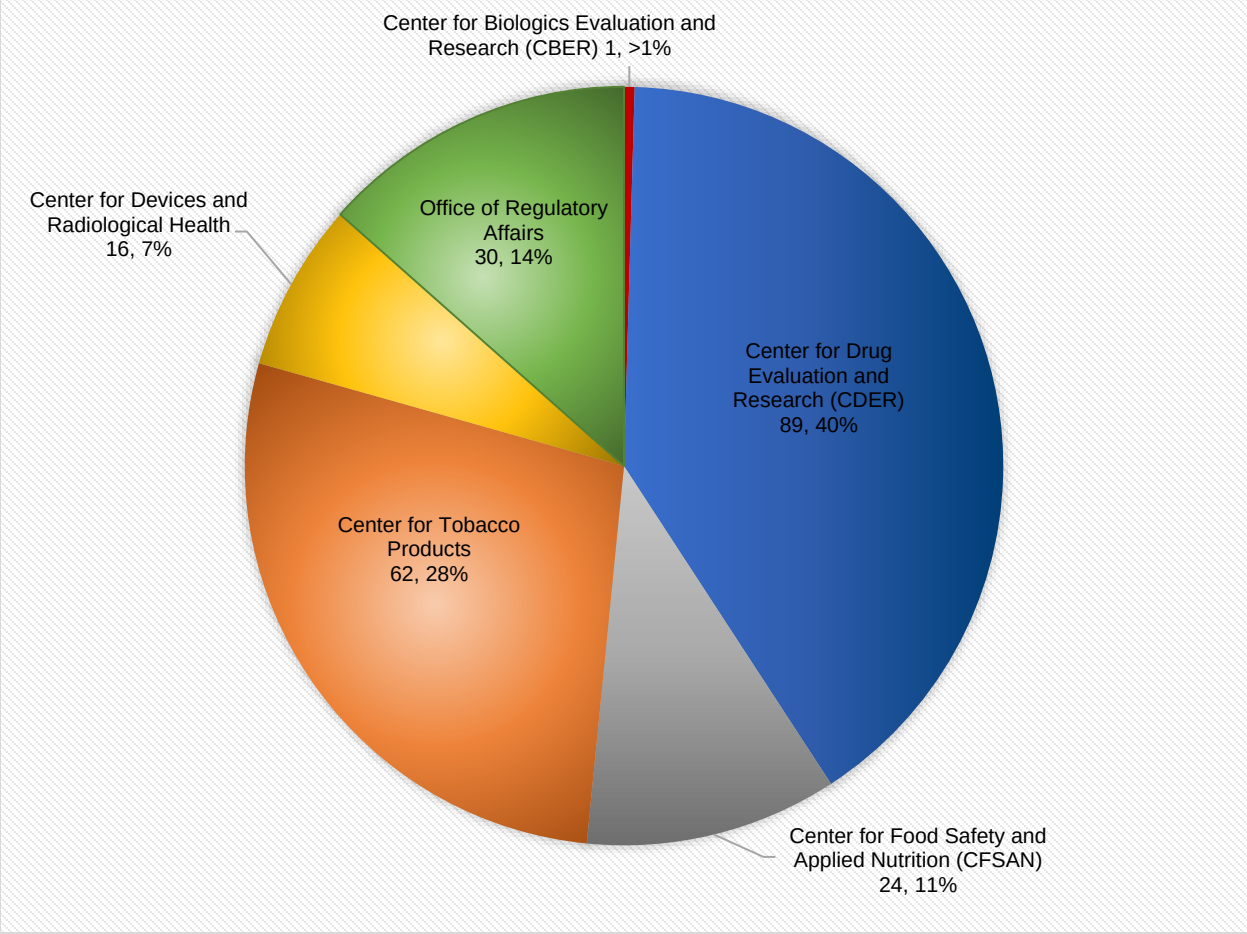
July 2020

FDA Enforcement Trends: Q2 2020

Toscano Consulting Group, Inc. (TCG) provides Quality and Regulatory consulting services to companies within the Pharmaceutical, Biologics, and Medical Device sectors. TCG continuously monitors FDA's Regulatory Enforcement activities to keep abreast of current regulatory enforcement trends. This newsletter provides a summary of Warning Letters issued from the various centers to deliver insight into FDA's active enforcement areas.

Now already halfway through the year, COVID-19 continues to be prominent on FDA's watchlist with over 70 Warning Letters issued during Q2 2020. This quarter the amount of Warning Letters issued by the FDA nearly tripled as they issued a total of 222 Warning Letters in Q2 of 2020 vs 75 in Q1. We saw an interesting shift in letters issued more so focusing on Medical Device products and companies rather than Pharmaceuticals and Biologic products as CDER seems to primarily set their focus on COVID-19 related product marketing and website distribution. The distribution by Issuing Centers is provided below in Figure 1.

FIGURE 1: WARNING LETTERS ISSUED BY CENTERS[1]



After assessing the full list we then focused on the 20 Warning Letters (excluding COVID-19) that specifically cited cGMP violations for Medical Device, Pharmaceuticals, and Biologics companies; that were primarily issued by CDRH, CDER, CBER, or ORA. Out of the 20 Warning Letters the top five reoccurring CFR citations are provided in Table 1 below.

TABLE 1: TOP CFR WARNING LETTER CITATIONS

Top CFR Citations	Description	Number of Citations	Percentage
21 CFR 820.30	Design Controls	9	45%
21 CFR 820.198	Complaint Files	6	30%
21 CFR 820.100	Corrective and Preventive Actions	5	25%
21 CFR 820.75	Process Validation	4	20%
21 CFR 820.70	Production and Process Controls	4	20%

Note: Percentages in the table above reflect the number of CFR specific citations within the 20 WLs issued for GMP violations.

The United States continues to maintain the lead in the number of Warning Letters issued followed by Canada, India, and South Korea (Table 2).

TABLE 2: Q2 GMP WARNING LETTERS BY COUNTRY

Country	Total Number of GMP WL	Percentage
USA	7	35%
Canada	2	10%
India	2	10%
S. Korea	2	10%
China	1	5%
Hungary	1	5%
Japan	1	5%
Romania	1	5%
Taiwan	1	5%
Thailand	1	5%
UK	1	5%

SUMMARY OF KEY INSPECTION POINTS

- 1 out of 14 (7%) of the foreign cGMP audits resulted in the FDA putting the inspected company on Import Alert.
- 5 out of 20 (25%) of the Warning Letters had recommendations for the companies to obtain a 3rd party consulting firm to assist with addressing the citations.
- 1 out of 20 (5%) of the Warning Letters had primarily Data Integrity focused citations.
- 3 months was the approximate average lag time between when a site is inspected and when a Warning Letter is issued. In some cases, Warning Letters were issued within an average 30-day time period (i.e. companies were cited for Unapproved Products Related to COVID-19), these were excluded from the average.

As previously anticipated, we are not yet seeing a reduction of Warning Letter Issuance in Q2, due to the letter issuance lag time. We are however seeing an overall reduction in inspections conducted as the FDA has performed only 1,725 domestic Pharmaceutical, Biologic and Medical Device audits to date.[2] Additionally, we have now seen our first remote audit generated Warning Letter from the FDA[3] and anticipate seeing an increase in remote audits in Q3 as a result of the current travel and onsite restrictions.

Please do not hesitate to contact us here at TCG with any questions you may have. We are always here to provide help and clarity. Wishing you and your family health and safety during these unprecedented times.

Sincerely,

George Toscano, TCG, President

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References:

[1] Note for those Warning Letters issued by certain offices such as the Office of Pharmaceutical Quality, they were grouped by the respective center (CDER).

[2] https://datadashboard.fda.gov/ora/cd/inspections.htm

[3] Issued by CFSAN