Breakfast with the Atlanta FDA District Office

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On December 12, 2013, Arnall Golden Gregory, LLP and the Regulatory Affairs Professionals Society hosted their annual "Meet the FDA" breakfast during which representatives from FDA's Atlanta District Office shared insight on compliance and enforcement-related topics. This year, the event featured Ingrid Zambrana, District Deputy Director, and Dawn Hines, Director of the District Investigative Branch.

Topics covered in the presentation included current import processes, how facilities are selected for inspection, and common mistakes in FD-483 responses. While we will not discuss all of the points made by FDA during its hour presentation, some of the points we found of interest included:

- One way to facilitate the review of an imported product is to voluntarily submit an Affirmation of Compliance code. FDA uses this information to determine which entries "MAY PROCEED" without FDA examination and which entries require further "FDA REVIEW." Affirmation of Compliance codes are available here[1].

- FDA has fully deployed a new risk-based screening system for imports. Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) uses automated data mining, pattern discovery, and open-source intelligence to provide automated queries of FDA databases. PREDICT has increased the number of automated, real-time "MAY PROCEED" decisions.

- With the new PREDICT system, the quality of the data an importer or filer submits to FDA matters more than ever. Poor data will increase the targeting of subsequent entry lines (importers and filers) and increase the likelihood of examination and/or sampling by the FDA.

- If a company hires a third-party filer with a history of providing poor-quality data, it will slow down the company's importation process. Import Filer Evaluations are available on FDA's website[2].

- The Import Trade Auxiliary Communications System (ITACS) is the internet portal for import trade. FDA is planning to expand the website to allow users to create accounts through which companies can receive Notices of FDA Action for their imports.

- The frequency of routine inspections for food facilities is mandated by the Food Safety Modernization Act. High risk foods are inspected every 3 years, and low risk foods are inspected every 7 years following enactment, and once every 5 years thereafter.

- For drugs and biologics, the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research provide the District Office with a list of inspections that it must complete during a fiscal year.

- One common mistake that companies make when responding to an FD-483 is failure to explain how they will correct the problem. Many companies respond that the problem will be corrected, but FDA expects details on how and when the issues will be resolved.

1 http://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM349883.pdf
2 http://www.fda.gov/ForIndustry/ImportProgram/ucm282834.htm

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