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FDA Inspection Proposal Provides Valuable Insight Into Scope of Investigations

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At yesterday's meeting with the U.S. House Subcommittee on Agriculture and Rural Development to discuss FDA's Fiscal Year 2019 budget, Food and Drug Administration (FDA) Commissioner Scott Gottlieb discussed the Agency's regulation of the tobacco industry and noted, among other things, that when all the requirements for the newly deemed products, including vapor products, went into effect last year, FDA now has authority to inspect and impose GMP standards and enforce age restrictions. Gottlieb indicated that FDA would be "stepping into this fight in a vigorous way in the coming weeks."

Being prepared for an FDA inspection is critical to maintaining compliance. Just a few weeks ago, FDA's recently-issued Request for Proposal (RFP), *Vape Inspection Services* (FDA-RFP-18-1190619), was extended on March 22, 2018 to allow for additional time for FDA to receive, review and consider responses from government contractors submitting bids to conduct inspections of establishments engaged in the retail sale of FDA-regulated tobacco products.

The RFP provides valuable insight into the Agency's current thinking with regard to the scope of inspections that are expected to begin shortly, as mandated by the Tobacco Control Act.

Specifically, the RFP indicates that the contractor(s) shall, in the course of a facility inspection:

- Complete and provide FDA with a signed Form FDA 482 ("Notice of Inspection");
- Complete an inspection form, detailing:
    - Administrative information;
    - The scope of the facility's business (*g.*, manufacturing, retail, import/export of products);
    - A list of potential violations of the Federal Food, Drug, and Cosmetic Act; and
- Be prepared to testify on behalf of FDA in any regulatory or judicial proceeding.

The RFP focuses extensively on the type of evidence collection and storage permissible under the Agency's guidelines – including the collection of photographic and physical evidence. The RFP further requires that the contractor complete required Agency training regarding the permissibility of collecting reports, data, documents, and photos (including limitations on Confidential Business Information (CBI), sales data, and personnel data).

The RFP describes the scheduling of inspections on a continuing, quarterly basis, in accordance with designated quotas. The program allocates funding for one full-time program manager, approximately 10 program coordinators, and 20 inspectors (based on 2,080 annual hours per full-time equivalent).

Daniel Rubenstein contributed to the post.

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