U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

May 6, 2014

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Subject: Responses to Questions Following GAO Testimony Entitled *TOBACCO PRODUCTS: FDA Spending and New Product Review Time Frames*

Dear Mr. Chairman,

On April 8, 2014, GAO testified at a hearing on examining the implementation of the Tobacco Control Act. The enclosed document is GAO's response to the Subcommittee's questions for the record. For questions regarding GAO's April 8 testimony and the following enclosure, please contact me at (202) 512-7114 or crossem@gao.gov.

Sincerely yours,

Marcia Crosse
Director, Health Care

Enclosure

cc: Sydne Harwick
John Stone
Carly McWilliams

Attachment I – Additional Questions for the Record

The Honorable John Barrow

1. **How do you assess FDA's capacity to regulate e-cigarettes?**

GAO has not conducted the work necessary to assess FDA's capacity to regulate e-cigarettes. In reporting on FDA's reviews of new tobacco product submissions, we noted that FDA has increased its staff and training for staff. However, tobacco industry stakeholders expressed concerns about whether FDA's Center for Tobacco Products (CTP) will have a sufficient number of qualified staff to review the backlog of the more than 4,000 new tobacco product submissions received as of December 31, 2013 in addition to the new submissions that may be made in the future, particularly if FDA asserts jurisdiction over new types of tobacco products that are not currently subject to FDA's regulatory authority.[1] CTP officials reported that many additional staff have been and will continue to be hired and trained, and the center does not expect hiring qualified staff to be a continuing challenge for the purpose of conducting product reviews.

In April 2014, FDA issued a proposed rule that, if finalized, would deem all products that meet the statutory definition of a tobacco product, including e-cigarettes, to be subject to FDA's regulatory authority.[2] It is not yet known whether the size of the backlog of new tobacco product submissions or FDA's resources to handle such a backlog will be different if FDA issues a final rule deeming e-cigarettes and other tobacco products not currently regulated by FDA to be subject to its authority.

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[1]GAO, *Tobacco Products: FDA Spending and New Product Review Time Frames*. GAO-14-508T (Washington, D.C.: Apr. 8, 2014), 13.

[2]79 Fed. Reg. 23142 (Apr. 25, 2014).

Attachment 2 – Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Gus Bilirakis

1. **Has FDA implemented the small business provisions included in the statute, including the establishment of the Office to Assist Small Tobacco Manufacturers for the provision of technical assistance? Has FDA issued any small business guidance?**

GAO has not conducted the work necessary to assess FDA's implementation of the small business provisions included in the statute. However, in conducting work on FDA's authority and resources to regulate the manufacture, marketing, and distribution of tobacco products, we have learned that FDA's Center for Tobacco Products (CTP) has conducted outreach and small business assistance activities, including establishing the Office of Small Business Assistance. Since fiscal year 2010, CTP and its Office of Small Business Assistance have responded to inquiries from small manufacturers and retailers, and provided information on relevant tobacco guidance and regulations, primarily through webinars. For example, in March 2012, FDA issued guidance to help small businesses understand and comply with FDA's tobacco product regulations, and, in August 2012, FDA held a webinar, Compliance Training for Small Businesses – *Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports.*[3] Officials from a trade organization representing small tobacco businesses reported that, in their view, provisions in the statute to protect small business have not been implemented by FDA as Congress intended. For example, although an Office of Small Business Assistance has been established by CTP, these officials said that small businesses still lack the technical, scientific, and other nonfinancial assistance they require. They told us that they had difficulty getting their questions answered by the Office of Small Business, often waiting months or even years for an answer.

The Honorable Renee Ellmers

1. **You stated that FDA continues to try to determine exactly what information they need in applications and the lack of that information prevents the Agency from moving forward in a timely fashion. A number of the initial applications did not contain information that FDA needed in order to reach decisions and some of those deadlines required that applications come in prior to FDA putting out guidance on what was needed. At what point did the FDA put out the guidance for those application requests?**

[3]The Food and Drug Administration Center for Tobacco Products, Guidance for Industry: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products – Small Entity Compliance Guide, accessed April 28, 2014, http://www.fda.gov/downloads/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm297536.pdf. For additional information on FDA compliance webinars, see http://www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm220111.htm (accessed April 28, 2014).

CTP officials told us that insufficient information from manufacturers in Substantial Equivalence (SE) submissions for new tobacco products has had the most significant impact on review times for those submissions. According to CTP officials, the majority of SE submissions were incomplete and required follow-up with manufacturers to obtain additional information, such as a full description of both the new tobacco product and the predicate tobacco product. CTP officials reported that they spent significant time sending out letters requesting missing information from manufacturers and awaiting the manufacturers' responses.

Industry representatives agreed that the lack of completeness of submissions had an impact on reviews, but they told us that guidance provided by CTP was neither timely nor adequate for manufacturers to provide what CTP would consider SE submissions with sufficient information. Manufacturers we interviewed said they were not able to include all information indicated in CTP guidance that was issued on January 5, 2011, for provisional SE submissions, which needed to be submitted by March 22, 2011, in order for those products to remain on the market provisionally. In addition, they reported that the January 2011 guidance did not direct manufacturers to include some information by the March 22, 2011, submission deadline that CTP later requested in its September 2011 draft guidance or Advice and Information letters, such as an environmental assessment (which is information used by CTP to determine the environmental impact of granting an SE submission).