FRANK PALLONE, JR., NEW JERSEY
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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

January 8, 2020

Mary Denigan-Macauley, Ph.D.
Director, Health Care
Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Dr. Denigan-Macauley:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, December 10, 2019, at the hearing entitled "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Wednesday, January 22, 2020. As previously noted, your responses to the questions in this letter, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by email in the Word document provided with this letter to Benjamin Tabor with the Committee staff (benjamin.tabor@mail.house.gov). A paper copy of your responses is not required. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Mr. Tabor at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachment

cc: Hon. Greg Walden, Ranking Member, Committee on Energy and Commerce
Hon. Diana DeGette, Chair, Subcommittee on Oversight and Investigations
Hon. Brett Guthrie, Ranking Member, Subcommittee on Oversight and Investigations

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program"

December 10, 2019

Mary Denigan-Macauley, Ph.D
Director, Health Care,
Government Accountability Office

The Honorable Brett Guthrie (R-KY)

1. GAO has recommended that FDA take steps to improve the accuracy and completeness of information in its catalog of drug firms subject to inspection. In 2010 and 2016 reports, GAO found that FDA took steps to improve information accuracy. What steps remain for FDA to improve the accuracy and completeness of information in its catalog of drug firms subject to inspection?

2. My understanding is that the GAO plans to evaluate the FDA's risk-based selection model that is used to prioritize inspections. What questions does GAO have about the risk-based selection model? As part of the risk-based selection model evaluation, will GAO assess the potential benefits of using alternative methodologies or models, such as a predictive risk model?

3. Has the FDA provided any data or studies to the GAO that support conducting preannounced inspections in foreign drug inspections over unannounced or short notice inspections?

4. In 2016, GAO reported that FDA had yet to determine whether the foreign offices meaningfully contribute to drug safety, because FDA has no formal process for assessing the offices' contributions. What are the GAO's recommendations for FDA to track foreign office accomplishments to assess the extent to which those offices help ensure drug safety?

5. In its 2010 report, the GAO recommended that FDA develop a strategic workforce plan to help recruit and retain foreign office staff. FDA released such a plan in March 2016, but there are still longstanding vacancies in the foreign offices. Your written testimony states that these vacancies raise questions about the implementation of FDA's workforce plan. What were the problems in the implementation?

    a. In addition to implementation issues, do you have any additional comments on FDA's workforce plan?

b. What does FDA need to do to improve retention and management of inspectors, particularly in foreign offices?

The Honorable H. Morgan Griffith (R-VA)

1. Besides banning imports to the United States, how can FDA protect the supply chain when a foreign facility refuses an FDA inspection? When an importation ban is placed on a manufacturer, what does FDA do about API it has already introduced into the United States?