

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

June 28, 2019

Dr. Norman E. Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to examine the Food and Drug Administration's (FDA) ability to ensure the safety of the nation's drug supply. Earlier this year, we wrote to FDA concerning a series of recalls involving drugs manufactured overseas that contained trace amounts of known carcinogens.¹ We appreciate the staff briefing FDA provided, and we are now writing to request additional information.

FDA's oversight of foreign drug manufacturing is a longstanding area of concern for the Committee. In 2016, the Government Accountability Office (GAO) found that FDA had never inspected nearly 1,000 foreign manufacturing facilities.² While FDA has increased the number of inspections of foreign manufacturers and nearly eliminated its backlog of uninspected firms, FDA's oversight of medical products manufactured overseas remains on GAO's most recent High Risk List.³ In addition, the recalls of contaminated blood pressure medications that we noted in our previous letter continue to expand.⁴

¹ Letter from Frank Pallone, Jr., Chairman, Greg Walden, Ranking Member, et al., House Committee on Energy and Commerce, to Scott Gottlieb, Commissioner, U.S. Food and Drug Administration (Feb. 13, 2019).

² Government Accountability Office, *Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, But Needs to Assess the Effectiveness and Staffing of Its Foreign Offices* (Dec. 2016) (GAO-17-143).

³ Government Accountability Office, *High Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas* (Mar. 2019) (GAO-19-157SP).

⁴ See, e.g., U.S. Food and Drug Administration, *FDA provides update on its ongoing investigation into ARB drug products; reports on finding of a new nitrosamine impurity in*

We remain concerned about whether FDA has the appropriate resources, policies, management practices, and authorities to oversee adequately foreign drug manufacturing. Therefore, please provide the following by July 12, 2019:

1. FDA's latest data on its foreign drug inspections program broken out by country and by risk category, including the total number of facilities, the number of facilities that have never been inspected, the number of facilities making active pharmaceutical ingredients (API), the number of facilities making finished dosage forms (FDF), the number of facilities that have been inspected only once for those firms registered with FDA before January 1, 2016, the frequency by which FDA inspects facilities, the average duration of an inspection for an API firm and for an FDF firm, FDA's goal for frequency of inspection, the number of inspectors available, and the percentage of inspections conducted by a single FDA inspector.
2. FDA's policies and procedures regarding how it prioritizes and selects facilities for inspections under its risk-based approach.
3. FDA's policies and procedures regarding how the Center for Drug Evaluation and Research (CDER) evaluates and classifies findings from inspections, including guidelines for determining CDER concurrence with inspection findings and classifications.
4. FDA statistics on CDER concurrence or nonconcurrence with proposed surveillance inspection classifications from inspectors for the past 3 years, including statistics on the number of inspections for which CDER downgrades or upgrades the classification. Please provide the statistics separately for both foreign and domestic inspections.
5. Unredacted Form 483, Establishment Inspection Report (EIR), and EIR attachments for the FDA inspections of Zhejiang Huahai Pharmaceutical (ZHP) from May 15 – 19, 2017, and July 23 – August 3, 2018.
6. ZHP's written response to FDA's Form 483 and EIR from FDA inspections of ZHP.
7. Unredacted memorandum of CDER's decision to reclassify the FDA inspection of ZHP (May 15 – 19, 2017).
8. Unredacted version of the November 29, 2018, FDA warning letter to ZHP, and ZHP's written response.

certain lots of losartan and product recall (Mar. 15, 2019) (press release); U.S. Food and Drug Administration, *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan) (accessed Jun. 5, 2019).

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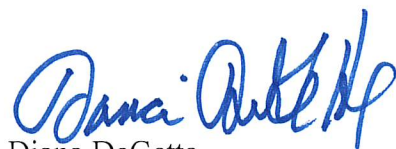
9. Unredacted Form 483, EIR, and EIR attachments for FDA's October 2017 inspection of Sichuan Friendly Pharmaceutical.
10. Unredacted Form 483, EIR, and EIR attachments for FDA's inspection (approximately January 2017) of Hetero Labs in Hyderabad, India.
11. Hetero Labs' written response to FDA's Form 483 and EIR from FDA inspection of Hetero Labs (approximately January 2017).
12. List of all FDA pilot programs of unannounced FDA drug inspections, the country, the date started, the date ended, the reason for discontinuing the pilot program, and list of all countries where FDA can conduct unannounced drug inspections.

An attachment to this letter provides additional information about responding to the Committee's request. If you have any questions, please contact Kevin McAloon of the Majority Committee staff at (202) 225-2927 or Alan Slobodin of the Minority Committee staff at (202) 225-3641. Thank you for your prompt attention to this matter.

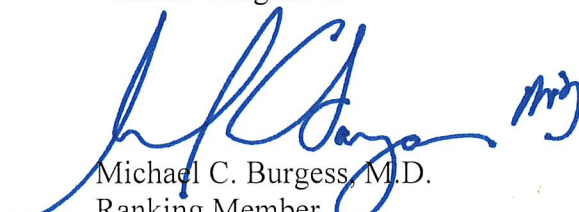
Sincerely,


Frank Pallone, Jr.
Chairman


Greg Walden
Ranking Member


Diana DeGette
Chair
Subcommittee on Oversight
and Investigations


Brett Guthrie
Ranking Member
Subcommittee on Oversight
and Investigations


Michael C. Burgess, M.D.
Ranking Member
Subcommittee on Health