Congress of the United States
House of Representatives
Washington, DC 20515

October 15, 2020

The Honorable Stephen Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

We write to express concern over the findings of a recent investigation by Consumer Reports that uncovered significant issues involving the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition's (CFSAN) Adverse Events Reporting System (CAERS). The investigation found that, through the misuse of so-called 'Exemption 4,' CFSAN is withholding from the public critical information on thousands of adverse events reports on dietary supplements that have caused harm. Consumer deserve access to this information in order to protect themselves and their families, and we urge you to immediately resolve this issue.

As you know, Exemption 4 is a reference to a regulation that permits the FDA to withhold a product's name from the public when a report of harm has been submitted voluntarily by a manufacturer. When the report of harm is considered serious, such as ones that result in hospitalization or death, a manufacturer is required to notify the FDA and the product's name is supposed to be publicized. Notably, reports submitted by consumers or doctors are not subject to Exemption 4. This exemption was designed to increase voluntary reporting of adverse events and prevent abuse of CAERS by competing companies or potential litigants.

However, according to the Consumer Reports investigation[1], the exemption has instead prevented critical information from being publicized and created a significant information gap in the CAERS data. Of the more than 19,700 products in the database, 15 percent are labeled as Exemption 4. In addition, the use of this exemption has increased significantly in recent years. In 2019, the FDA filed twice as many redacted reports as it had in the first decade of operating CAERS.

The FDA also appears to be applying Exemption 4 inconsistently, failing to publicize reports from consumers or doctors, or reports that describe events serious in nature. Consumer Reports found that, among more than 1,300 Exemption 4 reports for dietary supplements in CAERS, over one-third involved deaths or hospitalizations.

[1] *See*, https://www.consumerreports.org/dietary-supplements/fda-hid-names-of-dietary-supplements-linked-to-hundreds-of-reports-of-harm/

A representative from the FDA's FOIA division acknowledged in the report that some submissions were incorrectly labeled Exemption 4 due to "technical issues" and had no explanation for why the CAERS database had been experiencing problems. The agency also could not identify how many reports had been mislabeled.

Given that these problems with CAERS are preventing important safety information from reaching consumers, we request written responses to the following questions.

1. Please explain the technical issue that led to reports being incorrectly labeled as Exemption 4 in the CAERS database.
2. How long has this technical issue been occurring?
3. How many reports were incorrectly labeled as Exemption 4? Please provide a breakdown by product categories - foods, dietary supplements, and cosmetics.
4. What is the process the FDA uses to determine whether a submitted report is considered an Exemption 4 in the database?
5. The FDA uses CAERS to analyze reports to detect signals of adverse events linked to a product occurring more frequently than it would expect. What prevents the FDA from notifying the public that it is investigating a potential safety risk, much like it does under the FDA Adverse Events Reporting System (FAERS)?
6. When will the agency publish an updated version of the CAERS database?

Thank you for your attention to this matter. We look forward to your response.

Sincerely,

ROSA L. DeLAURO
Member of Congress

BETTY McCOLLUM
Member of Congress

Cc:
The Honorable Frank Yiannas, Deputy Commissioner, Food Policy and Response
The Honorable Susan Mayne, PhD Director, Center for Food Safety and Applied Nutrition (CFSAN)