

ONE HUNDRED FOURTEENTH 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

February 17, 2016

Dr. Stephen Ostroff
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Ostroff,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining the adequacy of FDA's procedures to protect the trade secret and confidential commercial information of regulated entities in the food industry. As described in greater detail below, the Food Safety and Modernization Act (FSMA) has recently expanded FDA's access to sensitive proprietary information. Recent cybersecurity breaches at FDA¹ and a criminal insider trading case involving an FDA official accessing information from drug review files in which he was not a part of the review team and did not have a need to know highlight the importance of FDA's ability to safeguard information security. Since FDA now has access to and possession of the most highly sensitive and proprietary information such as recipes and formulas, the committee seeks specific information from FDA on actions and plans for protecting this kind of information.

FDA has a legal obligation under the Food, Drug, and Cosmetic Act (FDCA) and federal criminal law to protect the trade secrets and confidential information of regulated entities. FDA is subject to Federal Information Security Management Act requirements and guidance issued by the National Institute of Standards and Technology under the Department of Commerce. In addition, when Congress passed the Bioterrorism Preparedness Act of 2002 and amended Section 414(a) of the FDCA to expand FDA's access to some food industry records, it required FDA to take additional, affirmative steps to protect sensitive information in its possession. Under this law, FDA must "take appropriate measures to ensure that there are in effect effective

¹ H. Comm. on Energy & Commerce, *Staff Report: Information Security at the Dep't of Health & Human Serv.*, 114th Cong. (Aug. 6, 2015).

procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by [FDA]...²

FSMA gives FDA access to additional records that may be classified as a trade secret or confidential information. For example, reports of regulatory audits by third party auditors and documents used to prepare those reports may be accessed by the FDA.³ FSMA also grants FDA the authority to access monitoring records, verification records, nonconformance and corrective action records, in the context of hazard analysis and risk-based preventative controls.⁴ In addition, FDA's recent proposed rule on the Nutrition Facts Label would require that regulated entities disclose additional information which may give FDA access to more proprietary information.⁵

The Committee seeks information to allow it to conclude that FDA has taken adequate measures to protect additional trade secret and confidential information entrusted to FDA. To assist the committee's examination, please provide the following answers and information by March 02, 2016.

1. The name and title of the official at the FDA's Center for Food Safety and Applied Nutrition (CFSAN) responsible for overseeing FDA's procedures to safeguard trade secret and confidential information. Please provide any documents showing how CFSAN is protecting such information, and also describe the efforts undertaken. Please also describe what efforts have been undertaken with FDA district offices to protect food industry trade secrets and other proprietary information. Is FDA aware of any corporate intelligence monitoring of FDA inspections, such as electronic surveillance of Internet transmissions from hotels where FDA inspectors stay during inspections?
2. How does FDA identify and classify trade secret and confidential information? Does the FDA consult with the company to determine whether certain information is a trade secret or whether certain information would be damaging to the company if disclosed? If not, why not? How would the FDA handle Freedom of Information Act (FOIA) requests that involve food industry trade secrets or confidential information? Would the FDA consult with the company who is the subject of the FOIA request to determine whether certain information potentially covered by the request was a trade secret or was otherwise highly confidential? If not, why not?
3. How does FDA determine which personnel may access trade secret and confidential information? How does FDA ensure that unauthorized FDA personnel do not have access to trade secret and confidential information? Does the FDA conduct any "need to know" assessments? If yes, please describe. If not, why not?

² 21 U.S.C. 350c(c).

³ 21 U.S.C 384d(c)(3)(B).

⁴ 21 U.S.C. 350g(g).

⁵ Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions, 80 Fed. Reg. 44303 (proposed July 27, 2015).

4. Do FDA personnel undergo specific training on FDA procedures protect trade secret and confidential information? If so, does this include FDA personnel in district offices and/or at CFSAN? If so, please explain the nature of that training.
5. How are documents with trade secret and/or confidential information maintained (electronically or paper format)? What systems are in place to prevent unauthorized reproduction of a document with trade secret and/or confidential information? Does FDA have any tracking system that would enable the agency to know if a document was copied and distributed to an unauthorized person?
6. How does FDA monitor the security of trade secret and confidential information in FDA's possession? For example, does FDA conduct security checks or audits? Have these been conducted at FDA district offices and/or CFSAN?
7. If a document with trade secret and/or confidential information is made public through unauthorized means, will FDA be able to determine which FDA personnel had custody of the document and was responsible for its disclosure?
8. How does the FDA monitor the electronic transmission of trade secret and confidential information?
9. Has FDA performed a risk assessment for the security of trade secret and confidential information within the last 10 years? If so, please explain the nature of all assessments conducted and the results.
10. Are there ever any circumstances in which FDA could make an authorized disclosure of a company's trade secret or commercial confidential information? If so, please describe those circumstances and the legal basis authorizing such disclosure.

Thank you for your assistance with this request. An attachment to this letter provides additional information about how to respond to the committee's request. If you have any questions regarding this request, please contact Alan Slobodin or Emily Felder with the majority committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Joseph R. Pitts
Chairman
Subcommittee on Health

Cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachments