

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

June 24, 2016

Dr. Robert M. Califf  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Dr. Califf:

Thank you for your letter of May 6, 2016, responding to the Committee's request for information about FDA's procedures to protect trade secret and confidential information of regulated entities in the food industry.

The Committee's concerns about FDA's procedures to protect trade secret and confidential information are underscored by an insider trading case brought by federal officials recently in New York. Prosecutors found that a political intelligence consultant and former FDA official unlawfully obtained the status and approval of a generic drug through contact with a current FDA senior official. The former FDA official provided the highly confidential information to a portfolio manager, who used the information to trade in the securities of two pharmaceutical companies likely to be affected by an approval of a generic enoxaparin application. As a result of the trading scheme, approximately \$25 million in trading profits were earned when the FDA announced its first such approval. The portfolio manager also tipped off a healthcare-focused hedge fund with material nonpublic information from the FDA, reaping millions of dollars in illegal profits.

Under the Food, Drug and Cosmetic Act (FDCA), the FDA has a legal obligation to protect trade secret and confidential information of regulated entities. From your initial response, it is clear that FDA has some procedures in place to protect trade secrets and confidential information. However, your response does not address how effectively FDA has implemented those procedures and controls, or how FDA audits employee compliance with these controls.

Please provide information on the effectiveness of the implementation of security procedures and controls and how FDA monitors employee compliance. Please also provide

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information about any additional steps FDA has taken to safeguard trade secret and confidential information in the wake of the federal charges in the insider trading case. To assist the Committee, please provide the requested explanation by Thursday, July 7, 2016.

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 J. Pallone, Jr., Ranking Member

The Honorable Gene Green, Ranking Member  
Subcommittee on Health