

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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August 13, 2013

Dr. Janet Woodcock
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

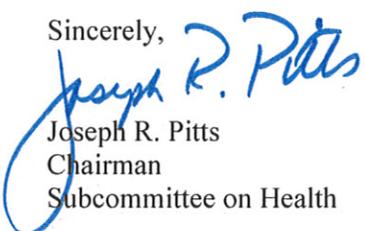
Thank you for appearing before the Subcommittee on Health on Tuesday, July 16, 2013, to testify at the hearing entitled "Reforming the Drug Compounding Regulatory Framework."

During the hearing, Members asked you to provide additional information for the record, and those requests are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose request you are addressing, (2) the complete text of the request you are addressing in bold, and (3) your response to that request in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Tuesday, August 27, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Attachment —Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable John D. Dingell

1. What authority does the FDA need to require all compounding pharmacies to register with the agency?
2. What authority does the FDA need to require all compounding pharmacies to report adverse events?
3. What authority does the FDA need to require all compounding pharmacies follow good manufacturing practices?
4. Does FDA believe nontraditional compounders should be subject to appropriate good manufacturing practices like manufacturers? Please elaborate.
5. Does FDA believe a risk-based inspection schedule is appropriate for nontraditional compounders? Please elaborate.
6. What authority does the FDA need to see all records when inspecting any compounding pharmacy?
7. Has FDA faced litigation regarding its ability to inspect records in pharmacies? Please elaborate.
8. Why does the FDA need this authority to effectively regulate compounding pharmacies?
9. Would the user-fee provisions contained in the Senate bill provide FDA with the necessary resources to carry out these authorities? Please elaborate.
10. Is the number of shipments by the compounder as important as to whom they are shipped and what the compounding might happen to be and who the individual is that is making the shipments? Please elaborate.

The Honorable Marsha Blackburn

1. On the ANDAs, you said you prioritize those applications. How long does it take to get one of those through the process? Please elaborate.