DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

APR 24 2013

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the April 9, 2013, hearing entitled "Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA." This letter provides the response to Representative Frank Pallone's request at the hearing for information about when a proposed rule entitled "Electronic Distribution of Prescribing Information for Human Drugs Including Biological Products" will be issued. The current Unified Agenda notes that the Food and Drug Administration's (FDA or the Agency) target date for issuing the proposed rule is June 2013. Mr. Pallone also asked for an update on the process moving forward.

While we can not provide a specific timeline or details of the proposed rule's contents prior to the issuance of the proposed rule, this is an issue of importance, and FDA continues to move forward on this proposed rule. Once the proposed rule is published, there will be a public comment period, during which time all interested stakeholders and the public will have the opportunity to provide FDA with their views on the substance of the proposed rule. Public comments are carefully reviewed by FDA and taken into account when drafting a final rule.

FDA agrees that electronic distribution of professional prescribing information will allow for more rapid distribution to health care professionals of the most up-to-date information about a prescription drug, including new warnings, contraindications, and directions for use, which would contribute to better care for patients, reduction in medication errors, and improved public health. Currently, the professional prescribing information containing the information for the safe and effective use of the product is distributed in the form of paper leaflets. Although the information in the professional prescribing information is a valuable resource, it may not contain the most current information because the paper leaflets accompanying a drug during distribution may have been printed and distributed prior to more recent labeling changes. The most common reasons for the printed professional prescribing information that is in the package on pharmacy shelves to be out of date are changes related to new approved uses for a drug already on

the market and new safety information detected from post-market use of the drug or from ongoing clinical trials.

FDA seeks to establish a modern and efficient process to distribute professional prescribing information to health care professionals. Because it takes time to prepare revised paper professional prescribing information, include it in the drug packages, and get those packages into distribution, the electronic distribution of professional prescribing information would help ensure that health care professionals have more rapid access to the most up-to-date information about the safety of marketed drugs.

Please let us know if you have any further questions.

Sincerely,

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce