4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 606, and 610

[Docket No. FDA-2007-N-0363]

RIN 0910-AG18

Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the Federal Register of December 18, 2014. In the proposed rule, FDA requested comments on its proposal to amend its labeling regulations for human prescription drugs and biological products to require that the prescribing information intended for health care professionals that is on or within the package from which the product is dispensed be distributed electronically and not in paper form, except as provided by the proposed rule. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published on December 18, 2014 (79 FR 75506). Submit either electronic or written comments by May 18, 2015.

ADDRESSES: You may submit comments to the proposed rule by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2007-N-0363 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6226, Silver Spring, MD 20993, 240-402-0980.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 18, 2014, FDA published a proposed rule to amend its labeling regulations for human prescription drugs and biological products to require that the prescribing information intended for health care professionals that is on or within the package from which the product is dispensed be distributed electronically and not in paper form, except as provided by the proposed rule. The proposed rule is intended to facilitate the distribution of updated prescribing information as new information becomes available and as changes in prescribing information are made. FDA is proposing the change to help ensure that the most current prescribing information will be available and readily accessible to health care professionals at the time of clinical decision making and dispensing. FDA provided a 90-day comment period (i.e., until March 18, 2015) for the proposed rule.

The Agency has received a request for a 60-day extension of the comment period for the proposed rule. The request conveyed concern that the current 90-day comment period does not allow sufficient time for entities and individuals who will be most affected by a final rule to examine and to comment upon the proposed rule. The request suggested that FDA would benefit by granting stakeholders sufficient time to develop their comments and to address as many relevant issues as possible.

FDA has considered the request and is extending the comment period for the proposed rule for 60 days, until May 18, 2015. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on this important issue.

II. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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