DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2007N–0114]

Electronic Distribution of Prescribing Information for Prescription Drug Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to [*insert date 45 days after publication in the* **Federal Register**] the comment period for the notice that published in the **Federal Register** of April 2, 2007 (72 FR 15701); this notice was related to the public hearing of April 27, 2007, concerning the electronic distribution of FDA-approved prescribing information currently contained in the package insert (PI) for prescription drug and biological products. FDA is reopening the comment period for the sole purpose of inviting interested persons to submit comments on the concept of electronic distribution of FDA-approved prescribing information currently contained in the PI for prescription animal drug products.

DATES: Submit written or electronic comments by [*insert date 45 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov.*

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FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, *Erik.Mettler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** notice of April 2, 2007 (72 FR 15701), FDA published a notice of public hearing concerning the concept of the electronic distribution of PIs for human prescription drugs and biological products and solicited relevant information and comments on this concept. The purpose was to garner views and information on the feasibility of establishing an efficient process for industry to electronically distribute prescribing information to dispensers. The PIs with prescribing information accompany prescription human drugs to meet the requirement that "labeling on or within the package from which the drug is to be dispensed bears adequate information for its use * * *" (21 CFR 201.100(c)(1)). For additional information, see the April 2, 2007, notice (72 FR 15701).

Currently, the PI contains the prescribing information for the safe and effective use of the product in the form of a paper leaflet. Although the information in the PI is a valuable resource, it is often not readily accessible when a healthcare provider who has not physically received the drug makes a treatment decision or discusses treatments with a patient. Additionally, the PI may not contain the most current information, because the PI accompanying the drug's distribution may have been printed and distributed prior to more recent labeling changes. Accordingly, with technological advances in the electronic transmission of information, we are considering how prescribing information could be more effectively disseminated.

FDA is reopening the comment period for the sole purpose of inviting interested persons to submit comments addressing a number of questions regarding the current use of package inserts for animal drug products and those logistical issues associated with electronic distribution of such prescribing information for animal drug products. The previous request for comments was limited to human drugs and biologics. As with prescription human drugs, the PIs with prescribing information accompany prescription animal drugs to meet the requirement that "labeling on or within the package from which the drug is to be dispensed bears adequate information for its use * * *" (21 CFR 201.105(c)(1)). FDA approves the prescribing information as part of both human and animal drug labeling in the drug application. The request for comment is to gain a better understanding of how PIs for animal drugs are currently used by healthcare entities as we consider new approaches for the dissemination of labeling information.

II. Issues for Discussion

FDA is specifically interested in receiving comments on the following questions and any other pertinent information related to the electronic distribution of the prescribing information for animals.

A. General

(1) Currently, who uses and benefits from the prescribing information?

(2) How can electronic distribution and access of the prescribing information be accomplished?

(3) Would electronic distribution and access of the prescribing information improve the public health?

(4) Would electronic distribution and access of prescribing information improve prescribing habits? If so, how?

(5) How might we ensure that changes in the distribution and access of the prescribing information will not negatively affect the current users?

(6) Would an increase in electronic access to prescribing information affect prescribers, pharmacists, clients and patients? If so, how?

(7) Are there any issues particular to the prescribing information for animal drugs that are dissimilar or distinct from those associated with human drugs and that might affect the feasibility of electronic distribution of labeling?

B. Logistics

(1) Generally and without focusing on vendor-specific methods, how can electronic distribution of prescribing information be accomplished?

(2) What are the costs associated with the successful implementation of electronic distribution and access to prescribing information, including startup and maintenance expenses? Please breakdown costs per healthcare sector.

(3) Is the technology and infrastructure currently available to accomplish electronic distribution and access? If so, what is available? If not, what is needed?

(4) What are other potential barriers to accomplishing the electronic prescribing information?

(5) How can we ensure that electronic prescribing information is accessible to those who need the information?

(6) How do we meet the needs of those who do not have electronic capability?

(7) In case of emergency or when a computer system is down, what might be the backup?

(8) How should electronically disseminated prescribing information be regularly updated and remain current?

(9) What are the roles for the involved parties (manufacturers, third-parties, health professionals, FDA, and consumers)?

(10) Should all products have electronic prescribing information or are there some products or classes of products that should continue to have paper prescribing information accompany the product?

(11) If electronic prescribing information were to be used instead of paper inserts, then how should electronic prescribing information be implemented? Should electronic prescribing information be phased in? If so, over what time period? Which products should use electronic prescribing information first?

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with

the docket number at the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p .m., Monday through Friday.

Dated: OCT 16 2007

October 16, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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