4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-D-0339]

Draft Guidance on Drug Safety Information–FDA's Communication to the Public; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance titled "Drug Safety Information – FDA's Communication to the Public." This draft guidance updates and revises the March 2007 guidance entitled "Drug Safety Information – FDA's Communication to the Public." This draft guidance describes FDA's current approach to communicating important drug safety information, including emerging drug safety information, to the public and the factors that influence when the information is communicated. The draft guidance was developed in connection with the Center for Drug Evaluation and Research's (CDER's) Safety First Initiative.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or Office of

Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Drug Safety Information – FDA's Communication to the Public." This draft guidance updates and revises a March 2007 guidance of the same name. It describes FDA's current approach to communicating important drug safety information, including emerging drug safety information, to the public and the factors that influence when the information is communicated.

For many years, FDA has provided information on drug risks and benefits to health care professionals and patients when that information has generated a specific concern, usually waiting until that information has been fully evaluated and has prompted an action, such as a revision to the drug's prescribing information. In recent years, FDA has tended to make information on potential drug risks available to the public earlier, often while the Agency is still evaluating the data and determining whether any action is warranted. FDA believes that timely communication of important drug safety information will give health care professionals, patients, consumers, and other interested persons access to the most current information concerning the potential risks and benefits of a marketed drug, helping them to make more informed individual treatment choices.

In the Federal Register of March 7, 2007 (72 FR 10224), FDA announced the availability of a guidance titled "Drug Safety Information – FDA's Communication to the Public." FDA has revised the 2007 guidance to provide updated information about its approach to communicating important drug safety information, including FDA's development of a single, standardized format for electronic drug safety communications about marketed drugs. In addition, the draft guidance describes FDA's posting of other safety assessments on its Web site in accordance with the requirements of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and to further our transparency objectives.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will replace the 2007 guidance and represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach

may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 310.305, 314.80, 314.98, 600.80, and in 21 U.S.C. 379aa have been approved under OMB Control Numbers 0910-0230, 0910-0291, 0910-0308, and 0910-0636.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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