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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0062]

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Certifier A. Corbin

**Guidance on Drug Safety Information—Food and Drug Administration'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 guidance titled "Drug Safety Information—FDA's Communication to the Public." This 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 such information is communicated. This guidance was developed in connection with FDA's Drug Safety Initiative. This guidance is the final version and supersedes the previously issued draft guidance titled "FDA's Drug Watch for Emerging Drug Safety Information" (70 FR 24606, May 10, 2005).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

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Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Seligman, Associate Director for Safety Policy and Communication, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5570.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled “Drug Safety Information—FDA’s Communication to the Public.” This 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 such information is communicated.

For many years, FDA has provided information on drug risks and benefits to healthcare professionals and patients when that information has generated a specific concern or prompted a regulatory action, such as a revision to the drug product’s labeling. FDA has been reexamining its risk communication program, including how and when we communicate emerging drug safety information to the public. More recently, FDA has begun taking a more comprehensive approach to making information on potential drug risks available to the public earlier, in some cases while the agency still is evaluating whether any regulatory action is warranted. FDA believes that timely communication of important drug safety information will give healthcare 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.

FDA's risk communication efforts are part of a larger drug safety initiative that began in November 2004, when FDA announced an initiative to strengthen the safety program for marketed drugs. This initiative included the following: (1) Sponsoring an independent study by the Institute of Medicine of the National Academies of the effectiveness of the drug safety system, with emphasis on postmarketing risk assessment and surveillance; (2) conducting workshops and Advisory Committee meetings regarding complex drug safety and risk management issues, including emerging concerns; and (3) publishing three risk management guidances. FDA augmented its drug safety initiative in February 2005 by creating an independent Drug Safety Oversight Board to enhance oversight of drug safety decision making within the Center for Drug Evaluation and Research (CDER).

In May 2005, FDA issued a draft guidance titled "FDA's Drug Watch for Emerging Drug Safety Information" (70 FR 24606, May 10, 2005). The draft guidance described a proposal to establish a new communication channel, called the "Drug Watch" Web page, to provide information to the public on emerging drug safety issues. In December 2005, FDA held a public hearing regarding "FDA's Communication of Drug Safety Information" that examined the various risk communication tools employed by FDA. FDA has carefully reviewed the comments it received on the draft guidance (30 comments were submitted to the public docket) and during the public hearing. This final version of the guidance reflects our consideration of these comments, as well as our experience with posting emerging drug safety information.

Due to potential confusion between the proposed “Drug Watch” and FDA’s existing “MedWatch” program, FDA no longer plans to use the name “Drug Watch” to describe the Web page that contains drug safety information. We have identified drugs that have been the subject of a Public Health Advisory or an Alert on a single Web page, the Index to Drug-Specific Information, linked from FDA’s Web site. This is part of our ongoing effort to use and enhance existing FDA communications mechanisms to better convey important drug safety information to the public. In addition, we have revised this guidance to describe the various methods FDA currently uses to communicate established and emerging drug safety information to the public. It should be noted that we will continue to evaluate and enhance the effectiveness of the various methods we use to communicate about important drug safety issues, including the mechanisms described in this guidance and the presentation of drug safety information on the Agency Web sites (<http://www.fda.gov> and <http://www.fda.gov/cder>). We intend to update this guidance, as appropriate, to reflect any substantial modifications to our communication of drug safety information to the public.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents 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.

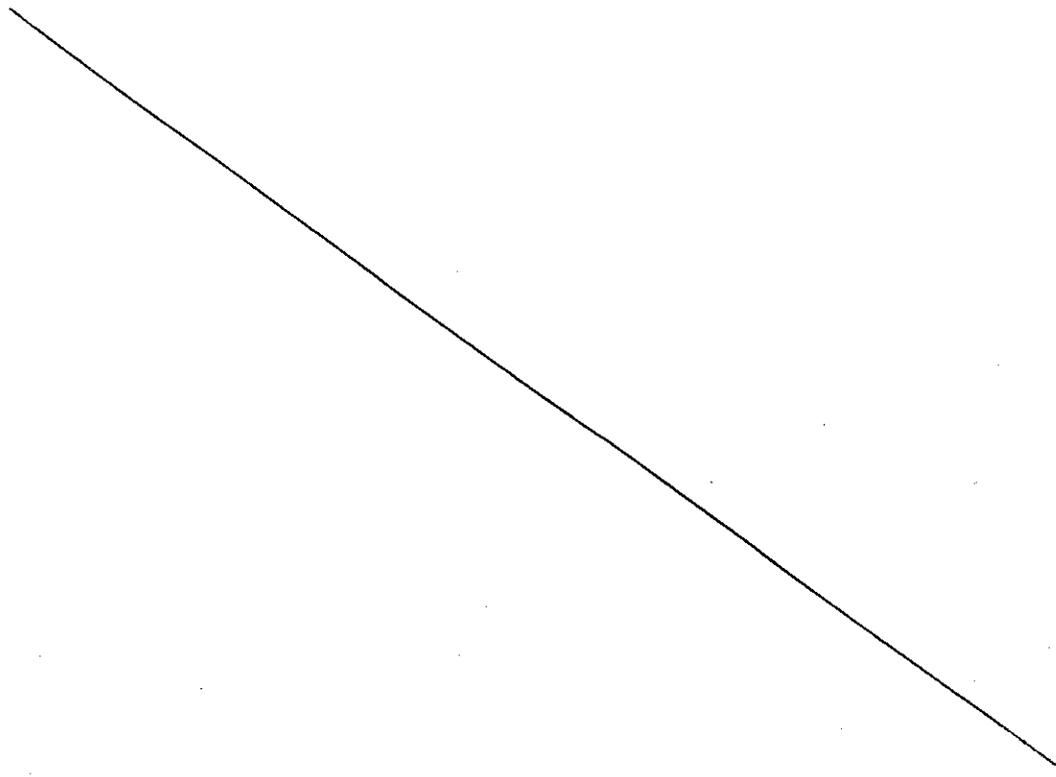
II. Comments

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 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 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

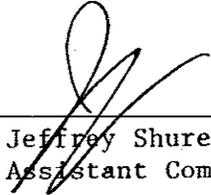
This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 310.305, 314.80, 314.98, and 600.80 have been approved under OMB control numbers 0910–0230, 0910–0291, and 0910–0308.



IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 2/28/07
February 28, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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COPY OF THE ORIGINAL**

