

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0062]

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Display Date	5/5/05 3:42
Publication Date	5/10/05
Center	R. LERESMA

Draft Guidance for Industry on the Food and Drug Administration's "Drug Watch" for Emerging Drug Safety Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "FDA's 'Drug Watch' for Emerging Drug Safety Information." This document provides guidance about how FDA intends to develop and disseminate important emerging drug safety information concerning marketed drug products to healthcare professionals and patients. This information will appear on an FDA Web page to be called the "Drug Watch."

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Deborah J. Henderson, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-5400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “FDA’s ‘Drug Watch’ for Emerging Drug Safety Information.” This document provides guidance about how FDA intends to develop and disseminate important emerging drug safety information concerning marketed drug products to healthcare professionals and patients.

In the last several months, members of patient groups, the medical community, and Congress have raised concerns regarding the way in which FDA has handled certain drug safety issues, most recently in connection with the withdrawal of Vioxx from the market and with the management of the risks of suicide associated with pediatric use of antidepressants. As a result, FDA is carefully evaluating its institutional approach to drug safety issues, focusing especially on the ways in which the agency responds to new safety concerns and resolves scientific disagreements about product safety between agency components. As part of this process, FDA is also reexamining its risk communication program, including how and when we communicate significant emerging safety information to healthcare professionals and patients.¹

¹ For information about the other steps FDA is taking see <http://www.fda.gov/bbs/topics/news/2004/NEW01131.html>.

FDA has long provided information on drug risks and benefits to healthcare professionals and patients. In the past, we provided that information when we were certain of its significance or it prompted a regulatory action, such as a labeling change. We have now decided to make important drug safety information available to healthcare professionals and patients in a new format and earlier than we have in the past. This information will appear on an FDA Web page called the "Drug Watch."

II. The Drug Watch Program

The goal of the Drug Watch program is to ensure that patients and healthcare professionals have quick access to the most up-to-date and accurate product information available in an easily accessible form. The Drug Watch Web page will post significant emerging safety information that FDA has received about certain drugs (or classes of drugs) while the agency continues to actively evaluate the information. The Drug Watch page is not intended to be a list of drugs that are particularly risky or dangerous for use; listing of a drug on the Drug Watch should not be construed as a statement by FDA that the drug is dangerous or that it is inappropriate for use. All drugs have risks, and prescribers must balance the risks and benefits of a drug when making judgments about an individual patient's therapy. However, sometimes after a drug is approved, rare but serious new side effects emerge as the drug is more widely used or is prescribed for off-label uses. Sometimes these emerging risks appear to be life-threatening, while in other cases they may appear to be less serious. In most instances, however, there is a period of uncertainty while FDA and the drug's sponsor evaluate new, emerging safety information to determine whether the safety concern in fact relates to the drug, and whether regulatory or other action is appropriate. The purpose of the Drug

Watch is to provide a forum from which FDA can communicate emerging safety information to the public while we continue to evaluate that information. We intend to work as quickly as possible to assess and address the safety issues identified on the Drug Watch, and we will continue to communicate important information about drug risks that are known with greater certainty using traditional means, such as public health advisories. Our goal with the Drug Watch is to share emerging safety information before we have fully determined its significance or taken final regulatory action so that patients and healthcare professionals will have the most current information concerning the potential risks and benefits of marketed drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on FDA's Drug Watch for emerging drug safety information. 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.

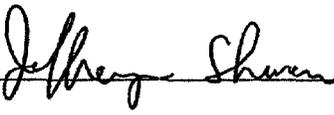
III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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: 5-4-05
May 4, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

