disposal—to be a source of information for health care practitioners, immediately recognizable as a statement from FDA, about a device risk with information on how to avoid or mitigate the risk. The purpose of this project is to evaluate the current notification format and distribution process for CDRH, with the goal of determining what is necessary to assure that the notifications reach, and are acted upon by, the target audience. The center needs to know that it is using the most effective approach to formatting and to disseminating PHNs to assure that they are received, recognized, understood, and acted upon quickly and effectively by medical practitioners and institutions. Considerations include, but are not limited to, design, terminology, nomenclature, distribution, utility of standardization, relationship with other medical product notifications (e.g., recalls), use of electronic transmission, and use of plain language.

The intent of this project is to determine the preferences of the health care community for learning from FDA about risks associated with medical devices and to compare the current process against the approach identified by the research to be ''preferred'' with the intent of improving our format and process.

CDRH will conduct a survey of a sample of health care providers who receive a new PHN from FDA. Most recently, FDA has been using intermediary organizations, such as professional associations, to help us distribute notifications to the appropriate target audiences and we are assuming that any new PHN will be disseminated in this way, using the appropriate association to distribute the PHN to their members. Generally, the PHN is distributed to the target audience electronically, either as a link embedded in a news article or sent directly via e-mail from either the professional association or FDA using the e-mail listing provided by the professional association. As part of the notification, we will provide a link to a Web-based questionnaire that will collect information related to the health care providers' preferences for learning about risks associated with medical devices.

The information collected in this survey will help FDA identify the most effective format(s) and distribution method(s) for CDRH PHNs.

In the **Federal Register** of January 9, 2006 (71 FR 1428), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Activity | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Survey of health care providers in relevant specialty | 300 | 1 | 300 | .1666 | 50 |
| Survey of health care providers in another relevant specialty | 300 | 1 | 300 | .1666 | 50 |
| Total | | | | | 100 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions and completing the questionnaire.

Dated: March 22, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–4440 Filed 3–27–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2001D–0489] (formerly Docket No. 01D–0489)**

### Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated March 2006. The guidance is intended to assist sponsors of clinical trials in determining when a data monitoring committee (DMC) is needed for study monitoring, and how such committees should operate. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated November 2001.

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

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800; or the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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*.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; Robert Temple,

Center for Drug Evaluation and Research (HFD–40), 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758; or Joanne Less, Center for Devices and Radiological Health (HFZ–403) 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a document entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated March 2006. The guidance is intended to assist sponsors of clinical trials in determining when a DMC is needed for study monitoring, and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs.

In the **Federal Register** of November 20, 2001 (66 FR 58151), FDA announced the availability of the draft guidance entitled ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated November 2001. FDA received a number of comments on the draft guidance and considered those comments carefully as the guidance was finalized. The final guidance also incorporates editorial and clarifying changes.

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

## II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 this guidance were approved under OMB control number 0910–0581.

## III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. 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. A copy of the 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 *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/cder/guidance.htm*, *http://www.fda.gov/cdrh*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 17, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–4428 Filed 3–28–06; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1998N–0046]**

### Annual Comprehensive List of Guidance Documents at the Food and Drug Administration

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

**DATES:** We welcome general comments on this list and on agency guidance documents at any time.

**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 *http://www.fda.gov/dockets/ecomments*. For information on a specific guidance or to obtain a hard copy of any of the guidances currently in use, contact the appropriate Center listed in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Regarding GGPs: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA's GGPs were published in the **Federal Register** of September 19, 2000 (65 FR 56468), and became effective October 19, 2000. GGPs (§ 10.115 (21 CFR 10.115)) are intended to ensure involvement of the public in the development of guidance documents, and to enhance understanding of the availability, nature, and legal effect of such guidance. In § 10.115(n)(2), FDA stated that it intended to publish an annual comprehensive list of guidance documents. The list in this document updates a comprehensive list that published January 5, 2005 (70 FR 824).

This year FDA has adopted a new format for its annual comprehensive guidance list. This new format is intended to increase the timeliness of the annual comprehensive list. For information on a specific guidance or to obtain a hard copy, please refer to the heading of each Center's section (sections II through VIII of this document). The list of guidance documents that have been withdrawn is for those guidances that have been withdrawn from January 5, 2005, to January 5, 2006. The list of current guidance documents is a printout of FDA's Web site as of January 31, 2006 or February 1, 2006. You are encouraged to use FDA's Web site as the most up-to-date source for all current guidance documents in use by the agency, as the Web site is updated on a daily basis.

In accordance with the agency's general policy on guidances, you may comment on this list and on any FDA guidance document at any time.

We have organized the documents by the issuing Center or Office within FDA. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. Because each issuing Center or Office maintains its own database, there are slight variations in the way in which they provide the information in this document.

## II. Center for Biologics Evaluation and Research (CBER)

For information on a specific guidance document or to obtain a hard copy, contact: Office of Communication, Training, and Manufacturers Assistance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, *http://www.fda.gov/cber/guidelines.htm*.