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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Janet M. Jones, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or Toni Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 2001 (66 FR 35797), FDA announced the availability of a draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format.'' As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. Recently the agency published a proposed rule to revise the overall format of prescription drug labeling (65 FR 81082, December 22, 2000). The agency also is developing a number of guidance documents that focus on the content of certain labeling sections. The first draft guidance entitled ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics'' was made available for public comment on June 21, 2000 (65 FR 38563).

The draft guidance entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format'' is the second guidance document on the content and format of individual labeling sections. Among other things, the draft guidance discusses what studies to include in the Clinical Studies section, how to describe those studies, and how to present clinical study data in graphs and tables. The agency also is trying to raise awareness, with this draft guidance, of the implications for product promotion of information contained in the Clinical Studies section. This section exists in the current labeling and is expected to continue to exist when the proposed rule to revise the format for prescription drug labeling is made final.

On October 1, 2001, FDA received a request from the Pharmaceutical Research and Manufacturers of America (PhRMA) to extend the comment period. PhRMA indicated that it needed additional time to coordinate comments from its member companies. In response to this request, and to provide all interested persons additional time to comment on this draft guidance, FDA is reopening the comment period until November 26, 2001.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: November 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–28961 Filed 11–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0489]

Draft ''Guidance for Clinical Trial Sponsors on the 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 draft document entitled ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated November 2001. The draft guidance document, when finalized, will assist sponsors of clinical trials in determining when a data monitoring committee (DMC) is needed for optimal study monitoring and how such committees should operate.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by February 19, 2002. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collections of information by January 22, 2002.

ADDRESSES: Submit written requests for single copies of the draft 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 (CDRH), 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 document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844; 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 draft guidance document.

Submit written comments on the document to the Dockets Management Branch (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), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758; or

Joanne Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated November 2001. The draft guidance document, when finalized, will assist sponsors of clinical trials in determining when a DMC is needed for optimal study monitoring, and how such committees should operate. The draft guidance addresses the roles, responsibilities, and operating procedures of DMCs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document 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 requirement of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees

Description: FDA is issuing a draft guidance document that will assist sponsors of clinical trials in determining when a DMC is needed for optimal study monitoring, and how such committees should operate. The draft guidance addresses the roles, responsibilities, and operating procedures of DMCs, and describes certain reporting and recordkeeping responsibilities including the following: (1) Standard operating procedures (SOPs); (2) interim reports by a sponsor to a DMC, statistical approach to FDA, DMC report of meeting minutes to the sponsor; and (3) meeting records. The information collection provisions for § 314.50(d)(5)(ii) (21 CFR 314.50(d)(5)(ii)) have been approved under OMB Control No. 0910–0001.

A. Standard Operating Procedures

Under the draft guidance, the agency recommends that all DMCs have well-defined SOPs. Subjects to be addressed in SOPs should include, but may not be limited to, the following:

- Schedule and format for meetings,
- Format for presentation of data,
- Identification of individuals who will have access to interim data to ensure confidentiality,
- Identification of individuals who may attend all or part of the DMC meetings,
- Method and timing of providing DMC members with interim study reports,
- Specification of the statistical approach that will be used to evaluate treatment effects and approach to considering early termination of the study for benefit or harm,
- Assessment of potential conflicts of interest of proposed DMC members,
- Interaction between FDA and DMC members for certain products, and
- Rapid unblinding of treatment codes to DMC members when needed.

The agency also recommends that the sponsor submit a description of the SOPs to FDA.

B. Interim Reports by a Sponsor to a DMC

The agency recommends in the draft guidance that the sponsor or sponsor's contractor submit an interim report, including information to be presented by the statistician at the DMC meeting, to the DMC. The interim report provides the DMC with essential information regarding the trial upon which they may base their recommendations.

C. Statistical Approach

The agency recommends in the draft guidance that the final statistical approach be submitted to FDA before initiation of interim monitoring. FDA reviews this information and may provide comments to the sponsor.

D. DMC Report of Meeting Minutes to Sponsor

The agency recommends in the draft guidance that the DMC issue a written report to the sponsor based on the meeting minutes. Reports to the sponsor should include only those data generally available to the sponsor. The sponsor may convey the relevant information in this report to other interested parties such as study investigators. Meeting minutes or other information that include discussion of confidential data would not be provided to the sponsor.

E. Meeting Records

The agency recommends in the draft guidance that the DMC or the group preparing the interim reports to the DMC maintain all meeting records. This information should be submitted to FDA with the clinical study report (§ 314.50(d)(5)(ii)).

Description of Respondents: The submission and data collection recommendations described in this document affect sponsors of clinical trials and DMCs.

Burden Estimate: Table 1 of this document provides the burden estimate of the annual reporting burden for the information to be submitted in accordance with the draft guidance. Table 2 of this document provides the burden estimate of the annual recordkeeping burden for the information to be maintained in accordance with the draft guidance.

Reporting and Recordkeeping Burdens

Based on information from FDA review divisions, FDA estimates there are currently 740 clinical trials with DMCs regulated by CBER, CDER, and CDRH. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 370 clinical trials. Because FDA has no information on which to project a change in the use of DMCs, FDA estimates that the number of clinical trials with DMCs will not change significantly in the next few years. For purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials,

resulting in an estimated 37 sponsors affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time would be necessary to revise or update them for use for other clinical studies. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of the meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial. Based on FDA's experience with the submission of investigational new drug applications (INDs), FDA estimates that one statistical approach per clinical trial would be submitted to FDA.

The hours per response and hours per record are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The hours per response include the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC, FDA, or the sponsor. Because clinical trials vary greatly in complexity, FDA estimates that the time needed to prepare and submit an interim report by a sponsor or sponsor's contractor to the DMC would generally range from 40 to 200 hours with an average of 120 hours for each report. The hours per record include the time to record, gather, and maintain the information.

The total estimated burden for both the reporting and recordkeeping burdens under the draft guidance are 93,684 hours.

FDA invites comments on this analysis of information collection burdens. FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
SOPs	37	1	37	4	148
Interim reports by the sponsor to a DMC	370	2	740	120	88,800
Statistical approach to FDA	370	1	370	8	2,960
DMC report of meeting minutes to the sponsor	370	2	740	1	740
Total					92,648

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOPs	37	1	37	8	296
Meeting records	370	1	370	2	740
Total					1,036

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

III. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document and on the collection of information. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by February 19, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch 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/index.htm, http://www.fda.gov/cdrh, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: November 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0464]

Vaccine Adverse Event Reporting System; Revised Form VAERS–2; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a proposed revised form entitled ''Vaccine Adverse Event Reporting System'' (Form VAERS–2) dated July 2001. This proposed revised form is intended to facilitate electronic reporting. The form has been revised by deleting data fields that FDA considers redundant or unnecessary, and by