

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
11.30	2,500	1	2,500	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of March 26, 2003 (68 FR 14663), FDA published a 60-day notice requesting public comment on the information collection provisions. Three comments were received. All three were submitted to the docket in error. One was a comment meant for the part 11 scope and application draft guidance. One was an opinion on medical device approvals. The last comment was questions from an individual related to electronic records.

Dated: July 17, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0142]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 22, 2003.

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on

the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry—Submitting and Reviewing Complete Responses to Clinical Holds—OMB Control Number 0910-0445—Extension**

Section 117 of the Food and Drug Administration Modernization Act (Public Law 105-115), signed into law by the President on November 21, 1997, provides that a written request to FDA from the applicant of an investigation that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. A clinical hold is an order issued by FDA to the applicant to delay a proposed clinical investigation or to suspend an ongoing investigation for a drug or biologic. An applicant may respond to a clinical hold.

Under section 505(i)(3)(C) of the Federal Food, Drug, and Cosmetic Act, any written request to FDA from the sponsor of an investigation that a clinical hold be removed must receive a decision, in writing and specifying the reasons, within 30 days after receipt of the request. The request must include sufficient information to support the removal of the clinical hold.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA published a notice of availability of a guidance that described how applicants should submit responses to clinical holds so that they may be identified as complete responses

and the agency can track the time to respond. After considering the comment received on that guidance, FDA issued a revised guidance in October 2000. In the **Federal Register** of April 21, 2003 (68 FR 19545), FDA published a notice requesting comment on this information collection. No comments were received pertaining to the information collection.

The revised guidance states that FDA will respond in writing within 30-calendar days of receipt of a sponsor's request to release a clinical hold and a complete response to the issue(s) that led to the clinical hold. An applicant's complete response to an IND clinical hold is a response in which all clinical hold issues identified in the clinical hold letter have been addressed.

The guidance requests that applicants type "Clinical Hold Complete Response" in large, bold letters at the top of the cover letter of the complete response to expedite review of the response. The guidance also requests that applicants submit the complete response letter in triplicate to the IND, and that they fax a copy of the cover letter to the FDA contact listed in the clinical hold letter who is responsible for the IND. The guidance requests more than an original and two copies of the cover letter in order to ensure that the submission is received and handled in a timely manner.

Based on data concerning the number of complete responses to clinical holds received by the Center for Drug Evaluation and Research (CDER) in fiscal year 2001 and 2002, CDER estimates that approximately 41 responses are submitted annually from approximately 29 applicants, and that it takes approximately 284 hours to prepare and submit to CDER each response.

Based on data concerning the number of complete responses to clinical holds received by the Center for Biologics Evaluation and Research (CBER) in fiscal year 2001 and 2002, CBER estimates that approximately 123 responses are submitted annually from approximately 78 applicants, and that it takes approximately 284 hours to

prepare and submit to CBER each response.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Complete Responses to Clinical Holds	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
CDER	29	approximately 1	41	284	11,644
CBER	78	1.58	123	284	34,932
Total					46,576

<sup>1</sup>There are no capital cost or operating and maintenance costs associated with this collection of information.

Dated: July 17, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0314]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the regulation requiring manufacturers, packers, and distributors of dietary supplements to notify FDA that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Submit written or electronic comments on the collection of information by September 22, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.fda.gov/ecomments>. Submit written comments to the Division of Dockets Management

(HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under 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 including each proposed extension of an existing 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.

#### Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control Number 0910-0331)—Extension

Section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act (21 U.S.C. 343).

*Description of Respondents:* Businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows: