

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

9787 '00 JUN 30 19 47

DMB

Display Date	7-3-00
Publication Date	7-5-00
Certifier	JN Reese

[Docket No. 00N-1224]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: 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: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105–115). Section 117 of the Modernization Act 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.

Section 505(i)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)(C)) requires that 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. FDA is now issuing a revised guidance.

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 investigational new drug application (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 in large, bold letters at the top of the cover letter of the complete response "Clinical Hold 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 FDA's contact, listed in the clinical hold

letter, who is responsible for the IND. The guidance requests more than an original and two copies, i.e., three 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) from July 1, 1998, to June 30, 1999, CDER estimates that approximately 48 responses are submitted annually from approximately 43 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 1999, CBER estimates that approximately 134 responses are submitted annually from approximately 110 applicants, and that it takes approximately 284 hours to prepare and submit to CBER each response.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Complete Responses to Clinical Holds	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	43	approx. 1	48	284	13,632
CBER	110	approx. 1	134	284	38,056
Total					51,688

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

In the **Federal Register** of April 13, 2000 (65 FR 19911), the agency requested comments on the proposed collections of information. No significant comments were received.

Dated: June 27, 2000



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

