

program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, and abuse in such program.

6. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, and abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, and abuse in such programs.

#### B. Additional Provisions Affecting Routine Use Disclosures.

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12-28-00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information." (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that because of the small size, use of this information could allow for the deduction of the identity of the beneficiary).

#### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

All records are stored on electronic media.

##### RETRIEVABILITY:

The collected data are retrieved by an individual identifier; *e.g.*, beneficiary name or HICN, and unique provider identification number.

#### SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

#### RETENTION AND DISPOSAL:

CMS will retain information for a total period not to exceed 25 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

#### SYSTEM MANAGER AND ADDRESS:

Director, Division of Deliver Systems Demonstration, Office of Research Development and Information, Mail Stop C4-18-03, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849.

#### NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, provider's tax identification number, national provider number, and for verification purposes, or the subject individual's name (woman's maiden

name, if applicable), HICN, and/or SSN (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

#### RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

#### CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

#### RECORDS SOURCE CATEGORIES:

Information maintained in this system will be collected from physicians volunteering to participate in the RHD. Additional data will be collected from Medicare claims payment records.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0211]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Proposed Collection; 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 a proposed collection of information 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 November 1, 2006.

**ADDRESSES:** 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: FDA Desk Officer, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Management Programs (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 on 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 (21 U.S.C. 355(i)(3)(C)), 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 issued a revised guidance in October 2000 which 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 (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 2 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 2004 and 2005, CDER estimates that approximately 88 responses are submitted annually from approximately 67 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 2004 and 2005, CBER estimates that approximately 92 responses are submitted annually from approximately 60 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	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
CDER	67	.76	88	284	24,992
CBER	60	1.53	92	284	26,128
Total					51,120

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

In the **Federal Register** of May 25, 2006 (71 FR 30142), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: September 26, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 2006N-0382]**

**Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance**

**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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Postmarket Surveillance under 21 CFR part 822.

**DATES:** Submit written or electronic comments on the collection of information by December 1, 2006.