DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0178]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Under the Federal Import Milk Act'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 7, 2005 (70 FR 58709), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0212. The approval expires on December 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–8114 Filed 12–29–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

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 January 30, 2005.

ADDRESSES: 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.

Submit written requests for single copies of the draft guidance dated December 2005 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. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

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

The draft guidance document, when finalized, 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 draft guidance was revised based on public comments. The draft guidance addresses the roles, responsibilities, and operating procedures of DMCs, and describes certain reporting and recordkeeping responsibilities including the following: (1) Sponsor notification to the DMC regarding waivers of expedited reporting, (2) DMC reports of meeting minutes to the sponsor, (3) sponsor reporting to FDA on DMC safety-related recommendations, (4) standard operating procedures (SOPs) for DMCs, (5) DMC meeting records, and (6) DMC reports to the sponsor.

A. Sponsor Notification to the DMC Regarding Waivers

The sponsor has the responsibility of reporting to FDA serious, unexpected adverse events in drugs and biologics trials under part 312 (21 CFR part 312) in § 312.32 and unanticipated adverse events in the case of device trials under part 812 (21 CFR part 812) in § 812.150(b)(1). We recommend in the draft guidance that sponsors notify DMCs about any waivers granted by FDA for expedited reporting of certain serious events.

B. DMC Report of Meeting Minutes to the Sponsor

FDA 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.

C. Sponsor reporting to FDA on DMC Safety-Related Recommendations

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (§ 312.32(c)) would not apply when the DMC recommendation is related to an excess of events not classifiable as

serious. Nevertheless, we recommend in the draft guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of ''serious.''

D. Standard Operating Procedures

In the draft guidance, FDA recommends that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;
- Ensure that those with serious conflicts of interest are not included on the DMC;
- Provide disclosure to all DMC members of any potential conflicts that are not thought to impede objectivity and, thus, would not preclude service on the DMC;
- Identify and disclose any concurrent service of any DMC member on other DMCs of the same, related or competing products;
- Ensure separation, and designate a different statistician to advise on the management of the trial, if the primary study statistician takes on the responsibility for interim analysis and reporting to the DMC; and
- Minimize the risks of bias that are associated with such arrangements, if the primary study statistician takes on the responsibility for interim analysis and reporting to the DMC, and it appears infeasible or highly impractical for any other statistician to take over responsibilities related to trial management.

E. Meeting Records

FDA 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) (21 CFR 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 revised 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 revised draft guidance.

Based on information from FDA review divisions, FDA estimates there are currently 740 clinical trials with DMCs regulated by CBER, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. 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 draft 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. FDA receives very few requests for waivers regarding expedited reporting of certain serious events, therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. 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.

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. The ''Hours per Record'' include the time to record, gather, and maintain the information.

In the **Federal Register** of November 20, 2001 (FR 66 58151), FDA published a 60-day notice requesting public comment on the information collection provisions in the draft guidance. FDA received a number of comments on the draft guidance, however, only one letter of comment included comments regarding the information collection provisions.

The comment stated that the ''Hours per Response'' were underestimated for the SOPs and Data Analysis Plan (statistical approach) listed in table 1 of the 60-day notice (66 FR 58151 at 58153) for the ''Estimated Annual Reporting Burden.'' The comment requested an increase to 12 hours for these burdens from the previous estimate of 4 hours for the SOPs, and 8 hours for the Data Analysis Plan.

In revising the draft guidance, FDA is adding the applicable regulations throughout the draft guidance including the regulations associated with these two burden estimates. The burden associated with the submission of SOPs and the statistical approach in table 1 of the 60-day notice is covered under §§ 312.23 and 812.150(b)(10) and is approved under OMB Control Nos. 0910–0014 and 0910–0078. Therefore, these categories were removed from table 1 and no change in the burden estimates is necessary.

Based on revisions to the draft guidance, however, two additional information collection burdens have been added to table 1 of this document, and one additional previous information collection burden was deleted from table 1 of the 60-day notice.

The information collection provisions in the draft guidance for §§ 312.30, 312.32, 312.38, 312.55, and 312.56 have been approved under OMB Control No. 0910–0014; § 314.50 has been approved under OMB Control No. 0910–0001; and §§ 812.35 and 812.150 have been approved under OMB Control No. 0190–0078.

The total estimated burden for both the reporting and recordkeeping burdens under the draft guidance are 1,794.75 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of Draft Guidance/ Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
4.4.1.2 Sponsor notification to the DMC regarding waivers of expedited reporting	1	1	1	.25	.25

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of Draft Guidance/ Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
4.4.3.2 DMC reports of meeting minutes to the sponsor	370	2	740	1	740
5 Sponsor reporting to FDA on DMC safety-related recommendations	37	1	37	.5	18.5
Total					758.75

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Reporting Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
4.1 and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2 DMC 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.

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–8115 Filed 12–29–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act System of Records

AGENCY: Indian Health Service (IHS), HHS.

ACTION: Amendment of one altered Privacy Act system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), the IHS has amended and is publishing the proposed alteration of a system of records, System No. 09–17–0001, ''Medical, Health and Billing Records.'' The amended and altered system of records makes only administrative edits and revisions as necessary.

DATES: The amended and altered system, which incorporates the comments received following the initial publication, shall become effective December 30, 2005.

FOR FURTHER INFORMATION: Contact Ms. Patricia Gowan, IHS Lead Health Information Management (HIM) Consultant (Acting), Office of Health Programs, Phoenix Area Office IHS, Two Renaissance Square, Suite 606, 40 North Central Avenue, Phoenix, AZ 85004 or via the Internet at *Patricia.Gowan@ihs.gov*.

SUPPLEMENTARY INFORMATION: As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), this document sets forth the amendment of the proposed alteration of a system of records maintained by the IHS, in response to comments received following the initial publication in the **Federal Register** at 70 FR 49931 on August 25, 2005. The purpose of altering System No. 09–17–0001, ''Health and Medical Records,'' is to enable the IHS to clarify that IHS also uses the records in the system to process, document, and monitor third-party payment billing and reimbursement claims, in addition to debt collection activities; to include contract health service records; to include several new and modified purposes and new and modified routine uses that are in line with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provisions and Agency policy changes. IHS published the notification of the altered Privacy Act system of records in the **Federal Register** on August 25, 2005. During the comment period, IHS received several responses from the public. After a careful review of their concerns, IHS does not agree with the suggested changes and therefore has not revised the notice. One of the commentors suggested revising routine use #10 so that it would provide an exception that would enable IHS to disclose patient health information for public health purposes. IHS has decided not to accept the recommendation of this comment because the IHS already complies with state laws that specifically require disclosures of health information for public health activities under the current routine use #7. In addition, the proposed routine use #10 modifies and replaces the current routine use #7 to allow disclosures ''as authorized by law'' which is a broader standard than the current ''as required by law'' standard. In fact, the particular example submitted by the commentor in support of the recommendation does not meet the public health authority and activities criteria of the HIPAA Privacy Rule. The Nevada State Pharmacy Board is not a public health authority and reporting such information to a state database appears to be primarily for law enforcement purposes. The Nevada statute also does not specifically require IHS or other Federal agencies to report to their database.

Another comment stated that ''IHS consider changing the permissive word ''may'' to the mandatory word ''shall'' in regards to the proposed Routine Use Number 23.'' In response to the comment, IHS has decided to reject the comment based on the fact that routine use disclosures are not mandatory but are discretionary disclosures made by the appropriate IHS Privacy Act System Manager for which is defined in the Privacy Act of 1974, as amended, 5 U.S.C. 552a; and the OMB Privacy Act Implementation Guidelines and Responsibilities of July 9, 1975.

The revision or modification of various IHS and Federal Records addresses in Appendix 1 and Appendix 2 is necessary to this system of records as administrative edits or changes. In Appendix 1, the address for the Fort McDermitt Clinic under the Phoenix Area IHS was inadvertently omitted;