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.

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees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