Dated: February 6, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. 2012–3114 Filed 2–9–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0793]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

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 March 12, 2012.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0432. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910–0432)—Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device, (2) immediately notify health professionals and device-user facilities of the order, and (3) instruct such professionals and facilities to cease use of such device.

Further, the provisions under section 518(e) of the FD&C Act set out the following three-step procedure for issuance of a mandatory device recall order:

1. If there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately:

- Cease distribution of the device,
- Notify health professionals and device user facilities of the order, and
- Instruct those professionals and facilities to cease use of the device;

2. FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device; and

3. After providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the Agency determines that such an order is necessary.

The information collected under the recall authority provisions will be used by FDA to do the following: (1) Ensure that all devices entering the market are safe and effective, (2) accurately and immediately detect serious problems with medical devices, and (3) remove dangerous and defective devices from the market.

In the **Federal Register** of November 16, 2011 (76 FR 71041), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) and (b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a), (b), and (c)	2	1	2	12	24
810.15(d)	2	1	2	4	8
810.15(e)	10	1	10	1	10
810.16(a) and (b)	2	12	24	40	960
810.17(a)	2	1	2	8	16
Total Hours	.....	.....	.....	.....	1,082

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
810.15(b)	2	1	1	8	8

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

The burden estimates for tables 1 and 2 of this document are based on FDA's experience with voluntary recalls under part 810 of the regulations. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily. Since the last time this collection of information was submitted to OMB for renewal/approval, there has been one mandatory recall.

Dated: February 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3098 Filed 2–9–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0096]

Draft Guidance for Industry on Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations.'' This guidance is intended to assist sponsors of clinical investigations in determining the amounts and types of safety data to collect in trials conducted late in the development of a drug for marketing approval or after approval based on what is already known about a drug's safety profile. Extensive safety data are collected in clinical trials of investigational drugs to support marketing approval (premarket) and trials conducted after approval (postmarket). FDA believes that more selective or targeted safety data collection may be possible for some late stage premarket trials and postmarket trials because certain aspects of a drug's safety profile will be sufficiently well-established that comprehensive data collection is not needed. FDA believes more selective or targeted safety data collection in appropriate circumstances may improve the quality of the safety assessment without compromising the integrity of the trial results.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 10, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6353, Silver Spring, MD 20993, 301–796–0210; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations.'' This guidance is intended to assist clinical trial sponsors in determining the amounts and types of safety data that should be collected during late-stage premarket and postmarket clinical investigations of a drug product based on what is already known about the safety profile of the drug.

To meaningfully weigh the risks and benefits of a drug, it is important to collect a broad range of safety-related data and develop a comprehensive safety profile of a drug. In some cases, however, certain aspects of the safety profile may be well-established prior to the completion of clinical trials to support marketing approval of an investigational drug. Similarly, for a marketed drug being studied for a new use, much of the existing safety profile for the approved use may be relevant to the new use. If certain aspects of a safety profile are well-established, it may not be necessary to collect certain types of safety data in clinical trials because the data would not contribute anything additional to the safety profile and may even have negative consequences (*e.g.,* serve as a disincentive to clinical investigators). In those settings, more targeted or selective data collection can be used to focus on collecting data that will further contribute to the safety profile.

The draft guidance identifies the types of safety data collected and recommends more selective or targeted safety data collection in a variety of circumstances, offers suggestions on methods that may be used to conduct selective or targeted data collection where appropriate, and highlights circumstances in which comprehensive data collection is generally needed.

This draft guidance is being developed consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on determining the extent of safety data collection needed in late stage premarket and postapproval clinical investigations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the