

know. At this time, the need-to-know senior management personnel are limited to 5 senior managers. Further, the data are used by this defined group only for decisionmaking and planning in the context of a federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by nondisaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices being tracked in the emergency shortages data collection system. In this initial call, the intent and goals of the data collection effort are

described, and the specific data request is made. After the initial call, one or more additional followup calls and/or electronic mail correspondence may be required to verify/validate data sent from the manufacturer, confirm receipt and/or request additional detail.

Although the regulatory officer is the agent who is initially contacted, they may designate an alternate representative within their organization to correspond subsequently with the CDRH EST member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities and raw

material/subcomponent sourcing, it is necessary to update the data in the ESDCS at regular intervals. This is done on a weekly basis, but efforts are made to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The ESDCS will only include those medical devices for which there will likely be high demand during a specific emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
903(d)(2)	125	3	375	0.5	188

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

FDA based the burden estimates in Table 1 of this document on past experience with direct contact with the medical device manufacturers, and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year to either obtain primary data or to verify/validate data. Because the data being requested represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0631]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical device recall authority.

DATES: Submit written or electronic comments on the collection of information by February 17, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810) for the medical device recall authority provisions. Section 518(e) of the 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 act sets out a three-step procedure for issuance of a mandatory device recall order which are: (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: (a) Cease distribution of the device, (b) notify health professionals and device user facilities

of the order, and (c) 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: (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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a-b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a-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-b)	2	12	24	40	960
810.17(a)	2	1	2	8	16
Total					1,082

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	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.

Explanation for Burden Estimates:

The burden estimates for Tables I and II 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 have been no mandatory recalls.

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comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: December 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0641]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the agency's Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments.

DATES: Submit written or electronic comments on the collection of information by February 17, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments (OMB Control Number 0910-0578)—Extension

The Operator's Manual contains information and recommendations for operators of retail and foodservice establishments who wish to develop and implement a voluntary food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles. Operators may decide to incorporate some or all of the principles presented in the manual into their existing food safety management systems. The recordkeeping practices discussed in the manual are voluntary and may include documenting certain activities, such as monitoring and verification, which the operator may or may not deem necessary to ensure food safety. The manual includes optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The Regulator's Manual contains recommendations for State, local, and tribal regulators on conducting risk-based inspections of retail and foodservice establishments, including recommendations about recordkeeping practices that can assist operators in preventing foodborne illness. These recommendations may lead to voluntary actions by operators based on consultation with regulators. For example, an operator may develop a risk control plan as an intervention strategy for controlling specific out-of-control foodborne illness risk factors identified during an inspection. Further, the manual contains recommendations to assist regulators when evaluating voluntary food safety management systems in retail and foodservice establishments. Such evaluations typically consist of the following two components: (1) Validation (assessing whether the establishment's voluntary food safety management system is adequate to control food safety hazards) and (2) verification (assessing whether the establishment is following its voluntary food safety management system). The manual includes a sample entitled "Verification Inspection Checklist" to assist regulators when conducting verification inspections of establishments with voluntary food safety management systems.

Types of operator records discussed in the manuals and listed in the following burden estimates include: (1) Food safety management systems (plans that delineate the formal procedures to follow to control all food safety hazards in an operation); (2) risk control plans (HACCP-based, goal-oriented plans for achieving active managerial control over specific out-of-control foodborne illness risk factors); (3) hazard analysis (written assessment of the significant food safety hazards associated with foods prepared in the establishment); (4) prerequisite programs (written policies or procedures, including but not limited to, standard operating procedures, training protocols, and buyer specifications that address maintenance of basic operational and sanitation conditions); (5) monitoring (records showing the observations or measurements that are made to help determine if critical limits are being met and maintained); (6) corrective action (records indicating the activities that are completed whenever a critical limit is not met); (7) ongoing verification (records showing the procedures that are followed to ensure that monitoring and other functions of the food safety management system are being implemented properly); and (8)