TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS (CBER)[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
312.160(c)	55	1.4	77	0.5	38.5

[1] There are no capital and startup, or operation, maintenance, and purchase costs associated with the collection of information requirements.

TABLE 6—TOTALS FOR ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS FOR CDER AND CBER

Reporting Burden	130,190,510
Recordkeeping	11,301,652
Total	141,492,162

Dated: February 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2846 Filed 2–10–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

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 Notification Procedure for Substances Generally Recognized as Safe.

DATES: Submit written or electronic comments on the collection of information by April 13, 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.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170.36 and 570.36 (OMB Control Number 0910–0342)—Extension

Section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the act (21 U.S.C. 321) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are Generally Recognized as Safe (GRAS) by qualified experts. In April 1997, FDA proposed a voluntary procedure whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS (62 FR 18938, April 17, 1997). Proposed §§ 170.36 and 570.36 provide a standard format for the voluntary submission of a notice. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the subject of the GRAS notice, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

Description of Respondents: Manufacturers of Substances Used in Food and Feed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
170.36	25	1	25	150	3,750
570.36	5	1	5	150	750
Total					4,500

[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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
170.36(c)(v)	25	1	25	15	375
570.36(c)(v)	5	1	5	15	75
Total					450

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

In the proposed rule, FDA estimated that the Center for Food Safety and Applied Nutrition (CFSAN) would receive approximately 50 GRAS notices per year and that the Center for Veterinary Medicine (CVM) would receive approximately 10 GRAS notices per year. Although FDA requested comment on this estimate, the comments did not provide useful information regarding this issue. Therefore, FDA evaluated the number of notices received by CFSAN to date. CFSAN received 274 GRAS notices during the 11-year period from 1998 through 2008, for an average of approximately 25 GRAS notices per year. Based on this experience, FDA is revising its estimate of the annual number of GRAS notices submitted to CFSAN to be 25 or less. FDA also is revising its estimate of the annual number of GRAS notices submitted to CVM to be 5 or less.

Dated: February 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2861 Filed 2–10–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0571]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Compliance With the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly ''Reprocessed Single-Use Device Labeling'')

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 13, 2009.

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, or e-mailed to *oira_submissions@OMB.eop.gov*. All comments should be identified with the OMB control number 0910–0577. Also include the FDA 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: 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 and Food and Drug Administration Staff; Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as Amended: Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly ''Reprocessed Single-Use Device Labeling'') (Federal Food, Drug and Cosmetic Act, Section 502(u)) (OMB Control Number 0910–0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) amended section 502 of the act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Thus, the name for this information collection activity has been changed to