and Federal officials have been formed to address the integration effort including one on roles and responsibilities of Federal, State, and Local agencies.

The Roles and Responsibilities Work Group, consisting of local, State, and Federal officials as part of the National Food Safety System (NFSS), has recommended the preparation of a resource assessment survey to determine the capacity and needs of State and local government agencies involved in food safety. The information will be collected by a contractor, to be determined, using a resource assessment questionnaire developed by the Roles and Responsibilities Work Group. The information gathered by the survey will help to determine what capabilities can be coordinated in each State and nationally and where there are gaps or insufficiencies that need to be addressed. The questionnaire will be provided electronically to State and local agencies for automated responses to minimize the reporting burden. Mail or facsimile hard copies will only be used for those jurisdictions that do not have electronic response capability. The resulting information will be computerized for analysis and reporting.

The survey will include questions on laws and regulations in effect; staffing; information systems; funding sources, mechanisms and amounts; staff training, certification, and qualifications; consumer and industry education; emergency response systems; laboratory resources and capabilities; epidemiology resources; official establishment inventories; routine inspection frequencies; surveillance sampling; minimum performance standards; program scope; and types of assistance needed from State and/or Federal agencies.

The questionnaire is intended to be a one-time effort but may involve additional contacts with respondents to clarify information supplied or to encourage participation. Responses to this questionnaire are voluntary. It should be noted that the State and local members of the Roles and Responsibilities Work Group have strongly endorsed the need for this survey so that informed and balanced recommendations can be made to policymaking and funding officials.

Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243) and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs relative to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Assistance to local, State, and Federal agencies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies.

There are approximately 4,200 local jurisdictions conducting food safety activities, about 150 State agencies, and an estimated 150 tribal agencies. More accurate counts will be available after the survey because one of the purposes will be to identify the local, State, and tribal agencies involved in food safety.

This will be a one-time survey with followup contacts to clarify responses or to elicit information from initial nonrespondents. Contact will be by electronic means whenever possible to minimize the burden on the respondent. Computerized data will be encouraged. FDA will likely contract with a third party to conduct the information gathering and compilation/analysis.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
4,500	1	4,500	4	18,000

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

Dated: March 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7934 Filed 3–30–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–5222]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of a Claim for GRAS Exemption Based on a GRAS Determination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by May 1, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Notice of a Claim for GRAS Exemption Based on a GRAS Determination (OMB No. 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 that act (21 U.S.C. 321(s)) 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. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. 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 GRAS claim, 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.

In the **Federal Register** of December 17, 1999 (64 FR 70714 at 70715), the agency requested comments on the proposed collections of information. No significant comments were received.

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	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

[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 of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(1)(v)[2]	50	1	50	15	750
570.36(c)(1)(v)[2]	10	1	10	15	150
Total					900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Due to a clerical error, the CFR cites that appeared in table 2 of the FEDERAL REGISTER of December 17, 1999 (64 FR 70714) were incorrect. Table 2 of this document contains the correct CFR cite.

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule; between January 1, 1999, and November 30, 1999, FDA received 23 notices. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: March 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7933 Filed 3–30–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M–1031 and 00M–1032]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; List of Premarket Approval Actions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval application (PMA) approvals. This list is intended to inform the public of the existence and the availability of summaries of safety and effectiveness of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the Internet at http://www.fda.gov/cber/appr1999/1999approv.htm. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document, when submitting a written request.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet at http://www.fda.gov, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of the PMA approvals announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)),