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
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a) and (c)	26	1	26	16	416
TOTALS					441

[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 Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20

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

Over the past 3 years, there has been an average of one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, FDA's Center for Devices and Radiological Health (CDRH) has had very few or no annual responses for this information collection and normally reports one response per year. CDRH is anticipating a banning action in Fiscal Year 2000 that will involve 26 firms.

Dated: March 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7932 Filed 3–30–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1061]

Agency Information Collection Activities: Proposed Collection; Comment Request; Resource Assessment of Programs and Services in Food Safety

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a project supported by FDA to collect information on food safety programs and services and the resources devoted thereto by State and local agencies nationwide.

DATES: Submit written comments on the collection of information by May 30, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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, 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: (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.

Assessment of Local and State Resources in Food Safety Programs and Services

In 1998, FDA began an effort, in cooperation with local, State, and other Federal agencies, to develop an integrated national food safety system. The system would coordinate the activities and resources of all levels of government devoted to regulatory food safety programs to maximize the impact of available resources, reduce overlapping functions, coordinate responses to foodborne disease outbreaks, share information, improve communications and training, establish minimum national uniform standards and identify gaps in food safety controls for correction at any level of government. The effort is consistent with the ''farm to table'' approach and sound scientific and risk-based priorities called for by the National Academy of Science's Report of August 20, 1998, and the President's Council on Food Safety, established by Executive Order 13100 on August 25, 1998. A number of workgroups of local, State,

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