of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on the following: (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.

Parts 171, 172, 173, 175–178, and 180 Food Additives and Food Additive Petitions (21 CFR Parts 171, 172, 173, 175–178, and 180) (OMB Control Number 0910–0016—Reinstatement)

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that any particular use or intended use of a food additive shall be deemed to be unsafe, unless the additive and its use or intended use are in conformity with a regulation issued under Section 409 of the act that describes the condition(s) under which the additive may be safely used, or unless the additive and its use or intended use conform to the terms of an exemption for investigational use. Food additive petitions are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 175–178, and 180 contain labeling requirements for certain food additives to ensure their safe use.

FDA scientific personnel review food additive petitions to ensure the safety of the intended use of the food additive in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food. FDA requires food additive petitions to contain the information specified in § 171.1 in order to determine whether a petitioned use for a food additive is safe, as required by the act. This regulation (§ 171.1) implements section 409(b)(2) of the act.

Respondents are businesses engaged in the manufacture or sale of food, food ingredients, or substances used in materials that come into contact with food.

FDA estimates the burden of complying with the information collection provisions of the agency's food additive petition regulations as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
171.1	44	1	44	2,876	126,560
Part 172	44	1	44	0	0
Part 173	44	1	44	0	0
Part 175–178	44	1	44	0	0
Part 180	44	1	44	0	0
Total	44				126,560

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

This estimate is based on the average number of new food additive petitions received in fiscal year 1995 and the total hours expended by petitioners to prepare the petitions. The burden varies with the complexity of the petition submitted, because food additive petitions involve the analysis of scientific data and information, as well as the work of assembling the petition itself. Because labeling requirements under parts 172, 173, 175–178, and 180 for particular food additives involve information required as part of the food additive petition safety review process under § 171.1, the estimate for the number of respondents is the same and the burden hours for labeling are included in the estimate for § 171.1.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32125 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0448]

Agency Information Collection Activities: Proposed Collection; Comment Request

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, 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 proposed survey of FDA Safety Alert and Public Health Advisory recipients.

DATES: Submit written comments on the collection of information by February 18, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600

Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 listed below.

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.

Survey of FDA Safety Alert/Public Health Advisory

Section 705(b) (21 U.S.C. 375(b)) of the Federal Food, Drug, and Cosmetic Act (the act) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of recent alerts include spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1701(a)(4) (42 U.S.C. 300u(a)(4)) of the Public Health Service Act authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly the problem discussed in the alert or advisory is identified, how easily the problem is understood, how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

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

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17	157

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

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time was estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey, in addition to discussions with contacts in trade associations.

Dated: December 11,1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32189 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–96–4000]

Memorandum of Understanding Between the Food and Drug Administration and the United States Customs Service

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the FDA and the United States Customs Service. The purpose of this MOU is to establish a partnership between both agencies to participate in an international trade Compliance Measurement (CM) Program.

DATES: The agreement became effective October 23, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas D. Gardine, Division of Import Operations and Policy, Office of Regulatory Affairs (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and other shall be published in the Federal Register, the agency is publishing notice of an MOU.