ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	60	1	60	88	5,280

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

This annual reporting estimate is based on information received from representatives of the food packaging and processing industries and on agency records. Typically, FDA receives 60 threshold of regulation exemption requests per year; these requests are equally divided between simple and complex type submissions. These requests require between 26 to 110 hours to prepare.

Dated: December 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31320 Filed 12–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0445]

Agency Information Collection Activities: Proposed Collection; Reinstatement

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, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's requirements for State and local governments' applications for exemption from preemption for medical device requirements.

DATES: Submit written comments on the collection of information by February 10, 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: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. FDA submitted a copy of this notice to OMB for its review of this information collection and requested emergency processing. OMB approved the information collection through March 31, 1997, and assigned OMB Control No. 0910–0129. Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (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 reinstatement 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 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.

Application for Exemption From Federal Preemption of State and Local Medical Device Requirements—21 CFR Part 808 (OMB Control No. 0910–0129—Reinstatement)

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)) provides that no State or local government may establish, or continue in effect, any requirement with respect to a medical device that is different from, or in addition to, any Federal requirement applicable to the device under the act. Under section 521(b) of the act, following receipt of a written application from the State or local government involved, FDA may exempt from preemption a requirement that is more stringent than the Federal requirement, or that is necessitated by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any portion of any requirement under the act. Exemptions are granted by regulation issued after notice and opportunity for an oral hearing.

The regulations in 21 CFR 808.20 require a State or local government that is seeking an exemption from preemption to submit an application to FDA. The application must include a copy of the State or local requirement, as well as information about its interpretation and application, and a statement as to why the applicant believes that the requirement qualifies for exemption from preemption under the act. FDA will use the information in the application to determine whether the requirement meets the criteria for exemption in the act and whether granting an exemption would be in the interest of the public health.

In addition, 21 CFR 808.25 provides that an interested person may request a hearing on an application by submitting a letter to FDA following the publication by FDA of a proposed response to the application.

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

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
808.20	3	1	3	100	300
808.25	3	1	3	10	30
Total Burden Hours	6	2	6	110	330

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

FDA based its estimates of the number of submissions expected in the future contained in the above table on the number of submissions submitted in the last 3 years and on the number of inquiries received indicating that applications would be submitted in the next year. FDA based its estimates of the time required to prepare submissions on discussions with those who have prepared submissions in the last 3 years. Persons are not required to respond to a collection of information unless it displays a valid control number.

Dated: November 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31321 Filed 12–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0266]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reinstatement

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 January 9, 1997.

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, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Judy V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Surgical Instrument Marking Tape Survey

The mandate of FDA's Center for Devices and Radiological Health under the authority of sections 201–905 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321–395), and regulations contained in Title 21 of the Code of Federal Regulations includes the approval and adequate labeling of medical devices. Section 903(b)(2)(c) of the act (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to medical devices.

The regulatory status of adhesive-backed, colored tape on medical devices is under review by FDA. The tape is frequently applied to medical devices, particularly surgical instruments, to facilitate sorting. It may be considered an accessory to medical devices used in surgical treatment as defined by 21 CFR 878.4800.

There are two case reports in the literature in which adverse events are attributed to the use of adhesive-backed, colored tape to mark surgical instruments (*Journal of Oral Maxillofacial Surgery,* 41:687–688, 1983; and *British Journal of Surgery,* 74:696, 1987). Two additional adverse event reports have been submitted to FDA.

The purpose of the survey is to estimate the proportion of the population at risk from this practice, and to determine if use of operating room nurse managers as proxies for sampling health care facilities for this purpose is effective. In addition, data will be collected to identify tape durability, extent of use, and whether there are any practices or procedures for marking surgical instruments and/or any human factors that could be altered to better protect the public health. Labeling information will also be collected.

The proposed randomized survey will be a one-time data collection effort. Completion of the survey is voluntary, and anonymity of individuals and institutions will be protected. Survey results will be available to participants upon request.

The only respondent burden will derive from the time needed to respond to survey questions. This will occur on a one-time basis. The length of the screening portion (questions 1–7) is estimated at 5 minutes, and the full survey length is estimated at an additional 25 minutes. Burden estimates are based on the need to have 308 surveys returned to achieve a statistically significant sampling.

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

ESTIMATED ANNUAL REPORTING BURDEN

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening Questions Only (30%)	92	1	92	0.083	7.63
Complete Survey (70%)	216	1	216	0.50	108
Total	308				115.63

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