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

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:

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
808.20	3	1	3	100	300
808.25	3	1	3	10	30
Total					330

[1] 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 Table 1 of this document 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.

Dated: January 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–992 Filed 1–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1502]

Agency Information Collection Activities; Announcement of OMB Approval; Quality Mammography Standards; Lay Summaries for Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Quality Mammography Standards; Lay Summaries for Patients'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of October 18, 1999 (64 FR 56210), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0426. The approval expires on December 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: January 10, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–987 Filed 1–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0683]

Agency Information Collection Activities; Announcement of OMB Approval; Record Retention Requirements for the Soy Protein/Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Record Retention Requirements for the Soy Protein/CHD Health Claim'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of October 26, 1999 (64 FR 57700 at 57726), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and

a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0428. The approval expires on December 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: January 10, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–988 Filed 1–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0260]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device Recall Authority'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of November 3, 1999 (64 FR 59775), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0432. The approval expires on December 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: January 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–989 Filed 1–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2097]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Humanitarian Use Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of October 25, 1999 (64 FR 57468), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0332. The approval expires on December 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: January 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–990 Filed 1–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0237]

Agency Information Collection Activities; Announcement of OMB Approval; New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of October 5, 1999 (64 FR 53960), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0423. The approval expires on December 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: January 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–991 Filed 1–14–00; 8:45 am]

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