Dated: January 11, 2000.

Barbara M. Williams,

Deputy Standard and Optional, Forms Management Officer.

[FR Doc. 00–1854 Filed 1–25–00; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–00–20]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

Continuing Medical Education (CME) Activity Registration Form—(0923–0013)—Extension—The Agency for Toxic Substances and Disease Registry (ATSDR) is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, The Superfund Amendments and Reauthorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment. As stated in CERCLA, the Administrator of ATSDR is charged to ''assemble, develop as necessary, and distribute to the states, and upon request to medical colleges, physicians, and other health professionals, appropriate educational materials (including short courses) on this topic''.

The development and use of activity registration forms for documenting participation in these activities at these meetings is an integral part of this process. This attendance documentation process is required by the Accreditation Council for Continuing Medical Education (ACCME), the body that authorizes agencies and institutions to award nationally recognized continuing medical education (CME) credit. As a condition of relicensure, physicians in 40 states are required to participate in CME courses. Individual physicians in these states are required to submit the number of hours of CME credit to state boards of professional registration at the time of relicensure. Failure by the physician to provide this information in a timely fashion will result in suspension of professional licensure.

This request is for a 3-year extension of the current OMB approval of uniform CME activity registration forms—one machine entry form and the other manually entered—to serve as the initial step in the development of an attendance documentation system. Other than their time, there will be no cost to the respondents.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response	Total burden
Manual Entry Registration Form	2,000	1	4/60	133
Scantron Registration Form	3,000	1	5/60	250
Total	.....	.....	.....	383

Dated: January 20, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–1762 Filed 1–25–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0595]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reporting and Recordkeeping Requirements for Manufacturers, Importers, User Facilities, and Distributors of Medical Devices Under FDAMA

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 (the PRA).

DATES: Submit written comments on the collection of information by February 26, 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: 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has

submitted the following proposed collection of information to OMB for review and clearance.

Reporting and Recordkeeping Requirements for Manufacturers, Importers, User Facilities, and Distributors of Medical Devices Under FDAMA

Description: The Food and Drug Administration Modernization Act of 1997 (FDAMA) contained provisions that affect medical device reporting in a variety of ways. Section 213 of FDAMA eliminated the reporting requirements for medical device distributors (but not for importers), as well as the certification requirements for medical device manufacturers and distributors. This section of FDAMA also modified the summary reporting requirements for user facilities to require annual, rather than semiannual, reporting, and increased confidentiality of user facility identities.

The final rule published elsewhere in this issue of the **Federal Register** amends FDA's regulations in part 803 (21 CFR part 803) and revokes part 804 (21 CFR part 804) to reflect the changes to medical device reporting made by FDAMA. The final rule has also been amended to implement the exemptions for manufacturers and distributors of cigarettes and smokeless tobacco products discussed in the next paragraphs.

In accordance with 5 CFR 1320.8(d), requests for public comment were published in the **Federal Register** of May 12, 1998 (63 FR 26069 and 63 FR 26129). Several comments were received in response to the proposed rule. A detailed discussion of the comments and FDA's response is included in the preamble to the final rule published elsewhere in this issue of the **Federal Register**.

Four comments objected that FDA did not follow the congressional recommendation in the conference report on FDAMA that FDA limit the time that distributors be required to keep records to a maximum of 6 years. The direct final rule required that distributors keep records for 2 years or the expected life of the device, whichever is greater.

FDA carefully considered the recommendations of the conference committee. The agency determined that the protection of the public health would not be adequately served if distributor recordkeeping was limited to a period of 6 years. Under the new quality system regulations contained in part 820 (21 CFR part 820), manufacturers (including initial distributors of foreign manufacturers) must retain records for a period equal to the design and expected life of the device (but no less than 2 years). The agency believes it is appropriate to require distributors to retain records for the same time period. This is especially important because distributors are no longer required to report any adverse event information to the agency, and the agency's primary access to the distributor complaint information is its periodic inspection and examination of the distributor records.

FDA considered electronic retention of distributor records. Prior to FDAMA and the proposed rule, the agency had not prohibited the electronic retention of records, nor did it intend to prohibit electronic recordkeeping based upon the proposal. When the distributor recordkeeping requirements were shifted from part 804 to part 803, the language remained largely unchanged. However, in order to avoid further confusion regarding electronic retention of records, the agency is modifying proposed § 803.18(d)(1) to clarify that distributor records may be either written or electronic.

Three comments stated that it is inappropriate to refer to the quality systems regulation (§ 820.198) in describing distributor recordkeeping because § 820.198 does not apply to distributors.

FDA agrees and has revised § 803.18(d) accordingly to remove the reference to § 820.198. FDA is substituting language to identify the relevant requirements from § 820.198 that apply to distributors who are not importers. However, FDA notes that § 820.198 does apply to importers of devices.

Two comments suggested that the reporting timeframe for importers should be changed to from 10 days to 30 days.

FDA agrees with these comments and has revised the final rule. Previously, importers were included in part 804 with the reporting requirements for distributors. Because distributors are no longer required to report, part 804 is eliminated and importers are included in part 803 with manufacturers. The 30-day timeframe is consistent with the timeframe for manufacturers.

One comment suggested that the form for reporting adverse events (FDA Form 3500A) should be revised to refer specifically to importers. Another comment asked for clarification as to whether a person who sells directly to the ultimate user may be considered an ''importer.''

The agency agrees that the fields to be filled out by importers on FDA Form 3500A should be specified within the regulation. Because the requirements and burdens would not be affected by revising the style and format of § 803.43, the agency is modifying the section to be consistent with §§ 803.32 and 803.52, which describe the information to be submitted on the MEDWATCH form. Proposed § 803.43 will be redesignated as § 803.42 in the final rule.

The agency notes that, because ''distributors'' had previously been defined to include ''importers,'' FDA Form 3500A does not specifically address importer information and does not use the term, ''importers.'' However, block F of the MEDWATCH form is identified for use by device user facilities and distributors. An importer should continue to complete blocks A, B, D, E, and F until the form is revised to remove references to ''distributor'' and replace them with ''importer.'' The agency clarifies that firms who purchase products from a foreign manufacturer and sell directly to the ultimate user are considered retailers and not importers under part 803, and they are not required to report.

One comment suggested that distributor reporting is important for the protection of the public health and recommended that, as an alternative to distributor reporting, FDA should require manufacturer contact information on the labeling to ensure proper adverse event reporting.

The agency agrees that consumers are likely to contact medical device distributors with their device complaints. Without distributor reporting, it is possible that the agency will not receive information regarding some complaints. However, under FDAMA, the agency no longer has the authority to require distributor reporting. Although FDA cannot require distributor reporting, FDA encourages distributors to report adverse event information to manufacturers so that they may investigate and report it as appropriate. The suggestion that FDA require manufacturer contact information on the labeling is beyond the scope of this rule and FDA will consider it separately.

One comment objected that FDA incorrectly interpreted section 422 of FDAMA regarding the regulation of tobacco products, tobacco ingredients, and tobacco additives. The comment stated that section 422 of FDAMA only means that nothing in FDAMA shall affect whether FDA has the authority to regulate tobacco products. The comment further said that section 422 of FDAMA does not mean, as FDA believes, that the requirements, such as medical device report (MDR) reporting, for manufacturers and distributors of

tobacco products are unchanged by FDAMA.

The agency disagrees with this comment. Section 422 of FDAMA states that ''Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive.'' Although this language may suggest that FDAMA is simply silent regarding the agency's authority to regulate tobacco, section 422 goes on to state that ''Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this act.'' Beyond the question of whether the agency has authority to regulate tobacco, this language directs the agency as to how it should exercise such authority once pending litigation is resolved.

Under section 422 of FDAMA, therefore, Congress neither affirms nor denies the agency's authority to regulate tobacco, but it does direct the agency to continue regulating tobacco as it had been doing prior to FDAMA (if authority to regulate tobacco exists). Prior to FDAMA, distributor reporting and manufacturer and distributor certification were required under the Federal Food, Drug, and Cosmetic Act (the act). If the agency were to exercise its authority under the act ''as in effect on the day before the date of the enactment of [FDAMA],'' distributor reporting and manufacturer and distributor certification requirements would continue to apply to manufacturers and distributors of cigarettes and smokeless tobacco products.

However, while the agency disagrees with the comment's interpretation of section 422 of FDAMA, FDA finds persuasive the comment's arguments that tobacco manufacturers should be exempt from the requirement of annual certification of MDR's and that distributors should be exempt from MDR reporting requirements under the residual authority of the act. The agency has authority under section 519(c) of the act (21 U.S.C. 360i(c)) to exempt, by regulation, any person from the medical device reporting requirements upon a finding that such reporting is not necessary to ''assure that a device is not adulterated or misbranded or * * * otherwise to assure its safety and effectiveness.'' The agency finds that the statutory criteria for exemption are met in light of the fact that Congress has repealed the requirements for manufacturer and distributor annual certification and distributor reporting. A reasonable assurance of the safety and effectiveness of tobacco products will be provided by the remaining medical device reporting requirements, that is, reporting and recordkeeping required of manufacturers and importers and recordkeeping required of distributors.

FDA estimates the burden for 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
803.15	50	1	50	4	200
803.19	150	1	150	3	450
803.22(b)(2)	100	1	100	0.25	25
803.33 (FDA Form 3419)	1,800	1	1,800	1	1,800
803.40	195	1	195	3	585
803.55 (FDA Form 3417)	1,000	20	20,000	1.1	22,000
Total					25,060

[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
803.17	2,000	1	2,000	3.3	6,600
803.18	39,764	1	39,764	1.5	59,646
Total					66,246

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

The burdens under the direct final rule (63 FR 26069) are explained in the following paragraphs.

I. Reporting Requirements

Prior to the program change reflected in this rule, distributors (including importers) were required to submit supplemental information under § 804.32. Distributors (who are not importers) are no longer required to submit MDR reports (including supplemental reports), and FDA has determined that it will not be necessary for importers to submit supplemental information except when FDA requests additional information under § 803.15. FDA has revised the final rule accordingly. Section 803.15 provides that FDA may request a reporter to submit additional or clarifying information concerning an MDR report when FDA determines that additional information is necessary for the protection of the public health. The burden estimate for § 803.15 includes only the burden for importers.

Prior to the program change reflected in this rule, § 803.19 allowed manufacturers or user facilities to request an exemption or variance from the reporting requirements. The agency had estimated that it would receive approximately 100 such requests annually. Distributors (including importers) were able to request an exemption or variance from the reporting requirements under § 804.33. Under this rule, § 803.19 is modified to transfer the exemption provisions for importers of medical devices from § 804.33 to § 803.19. Furthermore, distributors (who are not importers) of medical devices are no longer required to submit MDR reports under this rule.

The estimated burden for § 803.19 is further adjusted to reflect the agency's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.22(b)(2) provided that, if a manufacturer erroneously receives information about an adverse event concerning a device that they had not manufactured, the manufacturer must submit the report to FDA along with a cover letter explaining that the device in question was not manufactured by that firm. This final rule amends § 803.22(b)(2) to apply the same requirement to importers. The requirements of § 803.22(b)(2) were not previously reviewed by OMB under the PRA. Thus, the estimated burden reflects FDA's experience with this provision with regard to manufacturers and includes the estimated burden for both manufacturers and importers.

Prior to the program change reflected in this rule, § 803.33 required medical device user facilities to submit summary reports semiannually. Under this rule, user facilities are required to submit summary reports annually, thereby significantly decreasing the reporting burden on user facilities. The estimated burden for this section is also adjusted to reflect the agency's actual experience with this type of submission. FDA Form 3419 is being revised to reflect this change.

Under this rule the reporting requirement for importers of medical devices previously codified under § 804.25 is being transferred to § 803.40. The estimated burden for importer reporting is based upon the agency's actual experience with this type of submission. Section 803.40 requires importers to submit reports within 30 days after learning of the reportable event rather than 10 days as provided in § 804.25; this change does not affect the burden.

This rule does not amend § 803.55, but FDA is seeking approval for FDA Form 3417 on which baseline reports are to be submitted. The agency's estimate is based on FDA's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.57 required medical device manufacturers to annually certify as to the number of reports submitted during the previous year, or that no such reports had been submitted. Distributors (including importers) were required to certify under § 804.30. As stated previously, FDA is also exempting manufacturers and distributors of cigarettes and smokeless tobacco products from the requirement of annual certification. Therefore, under this rule, §§ 803.57 and 804.30 are being eliminated.

Because distributors, including distributors of cigarettes and smokeless tobacco products, will no longer be required to report, the final rule also removes §§ 804.25 (distributor reporting), 804.32 (supplemental information), and 804.33 (alternative reporting requirements).

II. Recordkeeping Requirements

Prior to the program change reflected in this rule, § 803.17 required manufacturers and user facilities to establish written procedures for employee education, complaint processing, and documentation of information related to MDR's. Under this rule, the requirements for establishing written MDR procedures for importers of medical devices have been transferred to § 803.17. The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information related to MDR reporting as part of their internal quality control system. The agency has estimated that no more than 2,000 such entities would be required to establish new procedures, or revise existing procedures, in order to comply with this provision. For those entities, a one-time burden of 10 hours, annualized over a period of 5 years, is estimated for establishing written MDR procedures. The remainder of manufacturers, user facilities, and importers not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Prior to the program change reflected in this rule, § 803.18 required manufacturers and user facilities to establish and maintain MDR event files. Distributors (including importers) were required to establish and maintain MDR event files under § 804.35. Under this rule, § 803.18 is modified to transfer the recordkeeping requirements for importers and other distributors of medical devices, including cigarettes and smokeless tobacco products from § 804.35; therefore, § 804.35 is removed. As discussed previously, this recordkeeping may be done in an electronic format.

Under the proposed rule, distributors of cigarettes and smokeless tobacco products would have been required to establish written internal procedures for evaluating and reporting events. Because distributors of cigarettes and smokeless tobacco products will not be required to report under the final rule, § 804.34 is removed.

Dated: January 18, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–1786 Filed 1–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

Food Labeling; Health Claims and Label Statements; Request for Scientific Data and Information; Reopening of Comment Period

Editorial Note: Due to a printing error FR Document 00–1127 did not appear in the printed version of the **Federal Register** on Wednesday, January 19, 2000. It is printed in its entirety below.

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for written comments; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 75 days the comment period for the submission of scientific data, research study results, and other related information on four substance-disease relationships that was announced in the **Federal Register** of September 8, 1999 (64 FR 48841). This action is being taken in response to requests for more time to submit data and information to FDA.

DATES: Written comments by April 3, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 8, 1999 (64 FR 48841), FDA requested scientific data, research study results, and other related information on four substance-disease relationships in order to reevaluate the scientific evidence for these relationships. FDA stated that it was taking this action to comply with a