Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW.; Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Attn: ACF Desk Officer.

Dated: October 27, 1999.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–28677 Filed 11–2–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0260]

Agency Information Collection Activities; Submission for OMB review; Comment Request; Medical Devices; Recall Authority

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 information collection by December 3, 1999.

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 20501, 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Recall Authority—21 CFR Part 810

Section 518(e) (21 U.S.C. 360h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) provides that if FDA finds that there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death, FDA shall issue an order requiring the appropriate person to immediately cease distribution of such device, immediately notify health professionals and device user facilities of the order, and instruct such professionals and facilities to cease use of the device. Under this statutory authority, FDA issued regulations under part 810 (21 CFR part 810).

The regulation in § 810.10(d) provides that FDA may require the person named in the cease distribution and notification order to submit certain information to the agency. Section 810.11(a) requires that a request for a regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA. In lieu of a written request for a regulatory hearing, the person named in the cease distribution and notification order may submit a written request asking that the order be modified or vacated as provided in § 810.12(a). Under § 810.12(b), a written request for review of a cease distribution and notification order must identify each ground upon which the requestor relies in asking that the order be modified or vacated and address an appropriate cease distribution and notification strategy. A written request must also address whether the order should be amended to require a recall of the device that was the subject of the order.

Section 810.14 states that the person named in the cease distribution and notification order or a mandatory recall order must develop a strategy for complying with the order that is appropriate for the individual circumstances and submit the strategy to the agency for review. Section 810.15(a) requires that the person named in the cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order, and § 810.15(b) through (c) prescribes the contents and implementation of such notification. Section 810.15(d) requires the person named in the order to ensure that followup communications are sent to all who fail to respond to the initial communications. Under § 810.15(e), recipients of such letters must follow instructions in the letter and notify consignees of the order. Section 810.16 requires that the person named in a cease distribution and notification order or a mandatory recall order submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports must be submitted will be specified in the order. Lastly, § 810.17 provides that the person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and must include a copy of the most current status report submitted to the agency.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to learn quickly about serious problems with medical devices, and to remove dangerous and defective devices from the market.

In the preamble to the final rule (61 FR 59004 at 59018, November 20, 1996), hereinafter referred to as the November 1996 final rule, the agency requested comments on the information collection provisions of the new regulation. The 60-day comment period closed January 21, 1997. The agency received two comments. The comments stated that: (1) The information collection requirements in this regulation are redundant and time and resource consuming, and (2) FDA should provide for the use of electronic media for complying with this rule.

FDA disagrees with the comment that the information collection requirements for the medical device recall authority are redundant and time and resource consuming. Almost all recalls are carried out under the voluntary recall procedures in part 7 (21 CFR part 7). As discussed in the November 1996 final rule, for cease distribution and notification orders and recall orders, FDA interprets the standard in §§ 810.10(a) and 810.13 to match closely to the elements of a class I voluntary recall under part 7, subpart C, for which the agency has a long record of experiences. FDA will initiate a mandatory recall under section 518(e) of the act when FDA finds that there is a reasonable probability that a device would cause serious, adverse health consequences or death. A firm may initiate a voluntary recall of a violative device without FDA intervention;

however, if FDA determines that such a voluntary recall is not effective in remedying a violation and there remains a reasonable probability that the violative device would cause serious adverse health consequences or death, FDA will invoke the medical device recall authority in addition to the voluntary efforts that the manufacturer has already undertaken. FDA will not order a mandatory recall if a voluntary recall has been effective in addressing the problems.

FDA believes that the November 1996 final rule provides sufficient flexibility so as to minimize the burden on those required to take action consistent with the determination that the device presents a risk of serious adverse health consequences or death. FDA expects that at most one or two recalls per year would be ordered that would not have occurred without this regulation.

In response to the comment regarding the use of electronic media for complying with these provisions, the regulation for electronic records and electronic signatures became effective March 20, 1997. Part 11 (21 CFR part 11) sets forth the criteria under which FDA will accept documents and signatures in electronic form in lieu of paper.

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
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) and (b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	1	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,082

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

FDA developed these estimates based on its experience with the number of voluntary recalls received in the last 3 years and other similar procedures.

Dated: October 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–28664 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4614]

Agency Emergency Processing Request Under OMB Review; Guidance for Industry; Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The collection of information is contained in a guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' The guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 116 of the Food and Drug Administration Modernization Act (the Modernization Act), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

DATES: Submit written comments on the collection of information by November 10, 1999.

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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Modernization Act (Public Law 105–115) into law. Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved NDA's and ANDA's, to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance for industry entitled ''Changes to an Approved NDA or ANDA'' provides recommendations to holders of NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

With respect to the collection of information described below, FDA invites comment 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,