DEPARTMENT OF HEALTH AND HUMAN SERVICES

OMB

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Food and Drug Administration

[Docket No. 2003N–0542]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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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.

Premarket Notification 510(k) Submissions—21 CFR Part 807 (OMB Control Number 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) requires a person who intends to market a medical device to submit a 510(k) submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. The definition of "person" has been expanded to include hospitals who re-use or re-manufacture single-use medical devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), added section 510(o) to the act to establish new regulatory requirements for reprocessed single-use devices (SUDs) (section 302(b) of MDUFMA, section 510(o) of the act). MDUFMA was signed into law on October 26, 2002. Section 301(b) of MDUFMA adds new requirements for reprocessed SUDs to section 510 of the act. The estimated submissions below include those submitted by hospitals re-manufacturing single-use medical devices.

Section 510(k) of the act allows for exemptions to the 510(k) submissions, i.e., a 510(k) submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process. Under 21 CFR 807.85, "Exemption from premarket notification," a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling and advertising by the manufacturer, importer, or

distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

One of MDUFMA's provisions requires the submission of validation data specified in the statute for certain reprocessed SUDs (as identified by FDA) such as cleaning and sterilization data, and functional performance data. FDA offers a guidance document to assist reprocessors of single use devices in submitting MDUFMA mandated validation data for the devices.

MDUFMA requires that FDA review the types of reprocessed SUDs not subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. MDUFMA also requires that FDA review critical and semi-critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submissions of 510(k)s to ensure their substantial equivalence to predicate devices. Under MDUFMA, FDA will use the validation data submitted for a reprocessed SUD to determine whether the device will remain substantially equivalent in terms of safety and effectiveness to its predicate

after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

FDA Form 3514 was developed to assist respondents in categorizing 510(k) data for submission to FDA. This form also assists respondents in organizing and submitting data for other FDA medical device programs such as premarket approval applications, investigational device exemptions, and humanitarian device exemptions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807 Subpart E (807.81 & 807.87–510(k))		4,000	1	4,000	80	320,000
	FDA 3514	2,000	1	2,000	.5	1,000
Submission of Validation Data (2003)		20	5	100	40	28,000
Totals						349,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [2]

21 CFR Section	Form No.	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
807.93		2,000	10	20,000	.5	10,000
Totals						10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document.

The total burden for using voluntary FDA Form 3514 is estimated to be approximately 1,000 hours and has been included in this collection of information. Once this collection of information has been approved, the burden for FDA Form 3514 will be reported and approved in each of the following OMB information collections: (1) Investigational device exemption reports and records (OMB control number 0910–0078), (2) premarket approval of medical devices OMB control number 0910–0231), and (3) medical devices, humanitarian devices (OMB control number 0910–0332).

Dated: 3/2/04

March 2, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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