Annually, FDA projects about 28 focus group studies using 186 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5194 Filed 3–8–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0079]

Agency Information Collection Activities; Proposed Collection; Comment Request; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ''Geriatric Use'' Subsection in the Labeling

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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the ''Geriatric Use'' subsection in the labeling for human prescription drugs.

DATES: Submit written or electronic comments on the collection of information by May 10, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, 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: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (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. Section 3506(c)(2)(A) of the PRA (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 extension 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ''Geriatric Use'' Subsection in the Labeling (OMB Control Number 0910–0370)—Extension

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the ''Precautions'' section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric patients (aged 65 and over). The information collection burden imposed by this regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

Section 201.57(f)(10) requires that a specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the ''Indications and Usage'' section of the labeling, and appropriate geriatric dosage must be stated under the ''Dosage and Administration'' section of the labeling. The ''Geriatric use'' subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. The data summarized in this subsection of the labeling must be discussed in more detail, if appropriate, under ''Clinical Pharmacology'' or the ''Clinical Studies'' section. As appropriate, this information must also be contained in ''Contraindications,'' ''Warnings,'' and elsewhere in ''Precautions.'' Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the ''Geriatric use'' subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. These statements are described further in § 201.57(f)(10).

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
201.57(f)(10)—new drug applications (NDAs)	73	1.48	108	8	864

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)—abbreviated new drug applications (ANDAs)	96	4.67	449	2	898
Total					1,762

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

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5195 Filed 3–8–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 April 8, 2004.

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.

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