contract requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements established by the MMA, and to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees. *Form Number:* CMS–R–267 (OMB #0938–0753); *Frequency:* Yearly; *Affected Public:* Business or other for-profit, and individuals or households; *Number of Respondents:* 9,000,670; *Total Annual Responses:* 9,000,670; *Total Annual Hours:* 7,711,085.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *April 15, 2008*:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 8, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–2813 Filed 2–14–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0077]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

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 proposed 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 present MedWatch Forms 3500 and 3500A (also known as MedWatch reporting forms) having an OMB expiration date of October 31, 2008. These forms are presently used to report to the agency about adverse events, product problems, and medication/device use errors that occur with FDA regulated products, including drugs, biologicals, medical devices, special nutritional products, dietary supplements, and non-prescription (over-the-counter (OTC)) human drug products marketed without an approved application.

DATES: Submit written or electronic comments on the collection of information by April 15, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (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.

MedWatch: The FDA Medical Products Reporting Program, Form FDA 3500 and Form FDA 3500A—(OMB Control Number 0910–0291)—Extension

Under sections 505, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 360b, 360c, 360e, and 393), and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417), 21 U.S.C. 342 is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event, product problem, or error with use of a medication or device occurs. Only if FDA is provided with such information will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, and 803.56.

Two forms are available from the agency in order to implement these provisions for reporting of adverse events, product problems, and medication/device use errors for FDA regulated products such as medications, devices, biologics, special nutritional products, cosmetics, dietary supplements, and non-prescription (OTC) human drug products marketed without an approved application, as well as any other products that are regulated by FDA. Form FDA 3500 may be used by health care professionals and the public for voluntary (i.e., not mandated by law or regulation) reporting. Form FDA 3500A is used by industry for mandatory reporting (i.e., required by law or regulation).

Respondents to this collection of information are health care professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biological and drug products or medical devices, and importers.

I. Use of Form FDA 3500 (Voluntary Version)

The voluntary version of the form is used to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the agency or the manufacturer, with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986 (Public Law 99–660). Those mandatory reports are not submitted to FDA on the 3500 or 3500A forms, but are submitted to the joint FDA/Centers for Disease Control and Prevention Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form (see: *http://www.vaers.hhs.gov/pdf/vaers_form.pdf*).

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

II. Use of Form FDA 3500A (Mandatory Version)

A. Drug and Biologic Products

In sections 505(j) and 704 of the act (21 U.S.C. 374), Congress has required that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biologics). Parts 310, 314, and 600 mandate the use of FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics.

Manufacturers whose name (under section 403(e)(1) of the act (21 U.S.C. 343(e)(1)) appears on the label of a dietary supplement marketed in the United States are required to report adverse reactions associated with use of the dietary supplement to FDA (the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462)).

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The Safe Medical Device Act of 1990 (Public Law 91–4243), signed into law on November 28, 1990, amends section 519 of the act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of FDA Form 3500A for reporting to FDA on medical devices.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), signed into law October 26, 2002, amended section 519 of the act. The amendment (section 303 of MDUFMA) required FDA to revise the MedWatch forms ''to facilitate the reporting of information * * *relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.''

Under section 303 of the FDA Amendments Act of 2007 (Public Law 110–85), FDA must share reports for Humanitarian Device Exemption (HDE) devices. To facilitate sharing the appropriate reports, it would be helpful to obtain the HDE number in the present section G, box 5, on page 2 of FDA Form 3500A.

III. Proposed Modifications to Forms

The proposed extension to Form FDA 3500 and Form FDA 3500A will only have changes in the form instructions to reflect the range of reportable products and provide clarity of reporting. The previous forms changes (2005–2008) allow reporters to better utilize available space for data entry and offer voluntary reporters the opportunity to clearly describe the suspected adverse event, product problem or error, and provide better quality safety-related data for agency evaluation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500	22,955	1	22,955	0.6	13,773

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

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	600	579.9	347,940	1.1	382,734
CDRH					
Form 3500	3,433	1	3,433	0.6	2,060
Form 3500A (Part 803)	1,935	33	63,855	1.0	63,855
CFSAN					
Form 3500	847	1	847	0.6	508
Form 3500A	0	0	0	1.0	0
Form 3500					16,341
Form 3500A					446,589
Total					462,930

[1]CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), and CFSAN (Center for Food Safety and Applied Nutrition). FDA Form 3500 is for voluntary reporting; FDA Form 3500A is for mandatory reporting.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2821 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0073] (formerly Docket No. 2002N–0418)

Agency Information Collection Activities: Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 proposed 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 information collection requirements relating to FDA's adverse experience reporting (AER) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit written or electronic comments on the collection of information by April 15, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Adverse Experience Reporting for Licensed Biological Products; and General Records —21 CFR Part 600 (OMB Control Number 0910–0308)—Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA is required to ensure the marketing of only those biological products which are safe and effective. FDA must, therefore, be informed of all adverse experiences occasioned by the use of licensed biological products. FDA issued the