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.

Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910–0482)—Extension

The total burden estimate of 43,214 is based on the number of notifications received by the relevant FDA centers in fiscal year 2004, or the last year the figures available.

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381). In general, the notification identifies the product being exported (e.g., name, description, and in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in section 802(b) of the act (21 U.S.C. 382), to any of those countries would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices animal drugs, foods and cosmetics that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the act.

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
1.101(d) through (e)	419	2.8	1164	17	19,788

[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 of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
1.101(b) through (c)	324	2.8	901	26	23,426

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

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28137 Filed 12–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0535]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: 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 revisions to Form FDA 3500 and Form FDA 3500A, (also known as MedWatch reporting forms). These forms are currently 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, and cosmetics.

DATES: Submit written or electronic comments on the collection of information by February 25, 2005.

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. Copies of Form FDA 3500 and Form FDA 3500A are available for public examination on

Internet at *http://www.fda.gov/ohrms/dockets* or in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. Submit written requests for single copies of the revised reporting forms, Form FDA 3500 and Form FDA 3500A to MedWatch: FDA Safety Information and Adverse Event Reporting Program (HFD–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request.

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:

I. Background

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: 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 (the DSHEA) (21 U.S.C. 341), section 402 of the act (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 parts 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, and 803.56.

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, and cosmetics, as well as any other products that are regulated by FDA, two forms are available from the agency. Form FDA 3500 may be used for voluntary (i.e., not mandated by law or regulation) reporting by healthcare professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation).

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

II. 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. Those mandatory reports are not submitted to FDA on the 3500 or 3500A form, 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.org/pdf/vaers__for.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.

Manufacturers of dietary supplements do not have mandatory requirements for reporting adverse reactions to FDA. The DSHEA puts the responsibility on FDA to prove that a particular product is unsafe. The agency depends on the voluntary reporting by health professionals and consumers of suspected adverse events associated with the use of dietary supplements.

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

A. Drug and Biologic Products

In sections 505(j) and 704 (21 U.S.C. 374) of the act, 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 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 form for reporting to FDA on adverse events that occur with drugs and biologics.

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 its safety and effectiveness. The Safe Medical Device Act of 1990, 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.''

IV. Proposed Modifications to Forms

The proposed modifications to Form FDA 3500 and Form FDA 3500A reflect changes that will bring the form into conformation with current regulations, rules, and guidances. Modifications were also made to better reflect the range of reportable products and language was changed slightly to provide clarity. The changes should allow reporters to better utilize available space for data entry and offer voluntary reporters the opportunity to better characterize the suspected adverse event, product problem or error and provide better quality safety-related data for agency evaluation.

In the proposed modification to current section D, Suspect Medical Device, the agency has relettered the form section and modified the formatting slightly, moving two of the data elements (''Device available for evaluation'' and ''Concomitant medical products'') to adjacent lettered sections on the form in order to improve the utilization of available space and allow for information on non-device products to share these data fields. The agency believes that these changes are compatible with the mandatory reporting instructions for devices (§ 803.33) and will allow mandatory reporters to continue to meet their reporting requirements.

FDA estimates the burden for completing the forms for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center/21 CFR Section	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
Form 3500A (§§ 310.305, 314.80, 314.98, 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	63,623	1.0	63,623
CFSAN					
Form 3500	847	1	847	0.6	508
Form 3500A (No Mandatory Requirements)	0	0	0	0	0
Total Hours					462,698
Form 3500					16,341
Form 3500A					446,357

(NOTE: 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).

The figures shown in table 1 of this document are based on actual fiscal year 2003 reports and respondents for each center and type of report.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0454]

Dietary Supplements; Premarket Notification for New Dietary Ingredient Notifications; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to February 1, 2005, the comment period for a notice that appeared in the **Federal Register** of October 20, 2004 (69 FR 61680). In the notice, FDA solicited comments on FDA's premarket notification program for new dietary ingredients (NDIs) and announced a public meeting on that topic. The comment period closed on December 3, 2004. FDA is reopening the comment period in response to a request from trade associations representing firms in the dietary supplement industry for additional time to submit comments.

DATES: Submit written or electronic comments by February 1, 2005.