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.

Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191)—Extension

Section 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e), the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
12.45	4	1	4	3	12

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

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23105 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0608]

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 revisions to Form FDA 3500 and Form FDA 3500A, and proposed consumer version of Form FDA 3500 (known as the MedWatch reporting form) used in the FDA Medical Products Reporting Program.

DATES: Submit either electronic or written comments on the collection of information by November 8, 2011.

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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov.*

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: The FDA Medical Products Reporting Program—(OMB Control Number 0910–0291)—Extension

To ensure the marketing of safe and effective products, postmarketing adverse outcomes and product problems must be reported for all FDA-regulated human health care products, including drugs, both prescription and over-the-counter (OTC); biologics; medical devices; dietary supplements and other special nutritional products (*e.g.,* infant formula and medical foods); and cosmetics. In addition, FDA has regulatory responsibility for tobacco products and an interest in receiving reports about adverse outcomes and product problems for these products.

Under sections 505, 512, 513, 515, 519, and 903 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355, 357, 360b, 360c, 360e, 360i, 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 FD&C Act (21 U.S.C. 352(f)(2)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the FD&C 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 502(t)(2) of the FD&C Act, devices are considered to be misbranded if there has been a failure or refusal to give required notification or to furnish required material or information required under section 519. 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, and specified in sections 760 and 761 of the FD&C Act. Mandatory reporting of adverse reactions for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) has been codified in 21 CFR 1271.350.

FDA regulates the safety (*i.e.,* adulteration) of dietary supplements under section 402 of the FD&C Act (21 U.S.C. 342). Dietary supplements do not require premarket approval by FDA and the Agency bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Under section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa–1(b)(1)), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States.

Mandatory reporting, since 1993, has been supplemented by voluntary reporting by health care professionals, their patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product or evidence of therapeutic failure (inequivalence) is suspected or identified in clinical use. When FDA receives this information from either health care professionals or patients, the report becomes data that will be used to assess and evaluate the risk associated with the product, and then FDA will take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these provisions for reporting on human medical products during their postapproval and marketed lifetimes, two forms are available from the Agency. Form FDA 3500 is used for voluntary (*i.e.,* not mandated by law or regulation) reporting by health care 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 health care professionals; medical care organizations and other user-facilities (*e.g.,* extended care facilities, ambulatory surgical centers); consumers; manufacturers of biological, dietary supplement, 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://vaers.hhs.gov/resources/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.

Under Federal law and regulation (section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa–1(b)(1))), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Therefore, the Agency depends on the voluntary reporting by health professionals and especially by consumers of suspected serious adverse events and product quality problems 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 FD&C 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 FD&C Act authorizes investigational powers to FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 parts 310 and 314 (drugs) and 600 (biologics) of the Code of Federal Regulations. Parts

310, 314, and 600 mandate the use of the FDA Form 3500A form for reporting to FDA on adverse events that occur with drugs and biologics. Mandatory reporting of adverse reactions for HCT/Ps has been codified in 21 CFR 1271.350.

The majority of the mandatory reports for drug products, which at inception of Form FDA 3500A's use were received by Agency on the paper version of Form FDA 3500A (by mail or FAX), are now submitted and received by the Agency via an electronic submission route. In that case, the Form FDA 3500A is not used.

B. Medical Device Products

Section 519 of the FD&C 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 FD&C 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 21 CFR part 803 (part 803). Part 803 mandates the use of the FDA Form 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002, Public Law 107–250, signed into law October 26, 2002, amended section 519 of the FD&C Act. The amendment (section 303) 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.''

C. Nonprescription Drug Products and Dietary Supplements

Section 502(x) in the FD&C Act (21 U.S.C. 352(x)) implements the requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription (OTC) human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements and nonprescription drugs.

IV. Proposed Modifications to Existing Forms 3500 and 3500A

A. General Changes

The proposed modifications to Form FDA 3500 and Form FDA 3500A reflect changes that will bring the form into conformation, since the previous authorization in 2008, with current regulations, rules, and guidances.

B. Changes Proposed for Form FDA 3500

No additional fields will be added and no fields deleted. There are no proposed formatting changes to the location or distribution of the fields. Modifications are proposed to several field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products and food (*e.g.,* food allergens causing allergic or anaphylaxis reactions). Descriptive text in the field labels and instructions were modified to permit a better understanding of data requested. For section E, field E4, the label ''Other'' will be renamed ''Unique Identifier #'' in anticipation of the use of this product information by the Agency for specific characterization and identification of the medical device. The form remains a one-sided, one-page form with instructions for use on the reverse side and a self-addressed, postage-paid return mailer.

C. Changes Proposed for Form FDA 3500A

Certain formatting changes are proposed to allow mandatory reporters to better utilize available space for data entry and facilitate specification of the device product's coding. In section D, field D2, it is proposed that the same field be used to request the procode (D2b) to correspond to the existing common device name (D2a). The D4 field currently named ''Other'' will be renamed ''Unique Identifier #.'' Section H, currently named ''Device Manufacturers Only'' will be renamed ''Manufacturers Only.'' Field H1 will have the ''Other'' checkbox removed, and field H6, renamed ''Event Problem and Evaluation Codes'' will have patient code and device code boxes added, as in the existing form's field F10. In section G, field G5, STN # will be relabeled BLA #. Given the need to contact mandatory reporters in a timely manner, the Agency proposes that a field be added to Form FDA 3500A to request an e-mail address for the mandatory reporter, to supplement the phone number and mailing address currently included on the form. This change is proposed for fields E1 and G1.

V. Proposed Addition of Consumer Version of Form FDA 3500

FDA supports and encourages direct reporting to the Agency by consumers (patients and their caregivers) of suspected serious adverse outcomes and other product problems associated with human medical products (*http://www.fda.gov/Safety/ReportaProblem/default.htm*). Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler, the program has been promoting and facilitating voluntary reporting by both the general public and health care professionals (Ref. 1). FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free telephone number or the MedWatch Internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children's Act (Pub. L. 107–109).

On March 25, 2008, section 906 of the FDA Amendments Act amended section 502(n) of the FD&C Act and mandated that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *http://www.fda.gov/medwatch,* or call 1–800–FDA–1088.'' Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit reporting via the MedWatch process and Form FDA 3500.

Currently, the non-health care professional public may submit voluntary reports using Form FDA 3500 (*http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm*). This reporting form was created 20 years ago, and modeled after an earlier version of the Agency's reporting form for health care professionals. Form FDA 3500 is provided in paper and electronic formats (HTML version at *http://www.fda.gov/medwatch/report.htm* and fillable pdf version at *http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm082725.pdf*), and is used to report to the Agency about serious adverse events, product

problems, product use errors, and therapeutic failure (therapeutic inequivalence). Reporting is supported for all FDA-regulated human medical care products, including drugs, biologicals, medical devices, special nutritional products, dietary supplements, cosmetics, and nonprescription (OTC) human drug products marketed without an approved application.

Qualitative assessment by social scientists, and comments and feedback from the public, have recognized that Form FDA 3500 is written and formatted at a literacy/comprehensibility level that far exceeds the level recommended for the general public by health literacy experts and does not conform to recommendations in the Plain Writing Act of 2010 (*http://www.gpo.gov/fdsys/pkg/PLAW–111publ274/pdf/PLAW–111publ274.pdf*).

The proposed consumer version of the voluntary Form FDA 3500 will request no new data from the voluntary reporter not already included in the existing Form FDA 3500 that is currently used for reporting from both health care professionals and consumers (patients). Certain existing fields, not considered essential data for the consumer report but present on the standard (i.e., health care professional) version of Form FDA 3500, have been eliminated to facilitate and expedite consumer submissions and reduce reporting burden. The formatting and the plain language used is compatible with the intent of the Plain Writing Act and is expected to provide non-health care professionals with a second option to the existing Form FDA 3500 that will reduce the burden of reporting by facilitating their understanding of the requested data and further clarify the voluntary reporting process.

The proposed consumer version of Form FDA 3500 evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the general public. The Agency recognizes that many consumer reporters have a preference for accessing a copy of the voluntary reporting form on the Internet or submitting to FDA using an electronic version of the form. The Agency currently supports voluntary reporting with the forms submitted by mail, by FAX, by telephone via the toll free 800 number and online at *http://www.fda.gov/medwatch/report.htm* . It is the Agency's expectation that an approved consumer version of the voluntary form will be provided for consumer use by these same channels.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center FDA Form (21 CFR Section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form 3500	28,952	1	28,952	0.6	17,371
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	599	96	57,504	1.1	63,254
Center for Devices and Radiological Health:					
Form 3500	4,585	1	4,585	0.6	2,751
Form 3500A (§ 803)	1,485	225	334,125	1.1	367,538
Center for Food Safety and Applied Nutrition:					
Form 3500	297	1	297	0.6	178
Form 3500A	1,039	1	1,039	1.1	1,143
Total					452,235

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

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kessler, D.A., ''Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems,'' *Journal of the American Medical Association,* vol. 269, pp. 2765–2768, 1993.

Dated: September 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23094 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0625]

Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 requirements for filing objections and requests for a hearing on a regulation or order.

DATES: Submit either electronic or written comments on the collection of information by November 8, 2011.

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