

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 03N-0016]

**Agency Information Collection Activities; Submission for OMB Review;  
Comment Request; MedWatch: The FDA Medical Products Reporting  
Program**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 information collection provisions 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 written comments be electronically mailed to [sshapiro@omb.eop.gov](mailto:sshapiro@omb.eop.gov) or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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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.

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

Under sections 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 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. A drug or device is misbranded under section 502(f)(1) of the act if its labeling does not bear adequate warnings for use, and under section 502(j) of the act 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 medication error 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 ranging from labeling changes to the rare product withdrawal. 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, 803.40, 803.50, 803.53, 803.56.

To implement these provisions for reporting of adverse events, product problems and/or medication error with medications, devices, biologics, and special nutritional products, as well as any other products that are regulated by FDA, two very similar forms are used. Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events, product problems and medication errors by health 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 professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, and manufacturers, packers, distributors, and importers of biological and drug products and medical devices.

## **II. Use of the Voluntary Version (FDA Form 3500)**

The voluntary version of the form is used to submit all adverse event, product problems, and medication error reports not mandated by Federal law or regulation.

Individual health professionals are not required by law or regulation to submit adverse event, product problem, or medication error 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 submitted by physicians 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 version), rather than the FDA 3500 or 3500A forms.

Hospitals are not required by Federal law or regulation to submit adverse event reports, product problems, or medication errors associated with medications, 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 illnesses or injuries.

Manufacturers of dietary supplements do not have to prove safety or efficacy of their products prior to marketing, nor do they have mandatory requirements for reporting adverse reactions to FDA. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. The agency is dependent on the voluntary reporting by health professionals and consumers of suspected adverse events associated with the use of dietary supplements.

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

#### *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 (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 the FDA Form 3500A form for reporting to FDA on adverse events that occur with drugs and biologics.

(Note: Most pharmaceutical manufacturers already use a 1-page modified version of the 3500A form where section G from the back of the form is substituted for section D on the front of the form.)

### *B. Medical Device Products*

Section 519 of the act (21 U.S.C. 360i) requires manufacturers, packers and distributors 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 amended section 519 of the act to require 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 requires the use of the FDA Form 3500A for mandatory reporting to FDA on medical devices.

The Food and Drug Administration Modernization Act of 1997 eliminated the reporting requirements for domestic distributors of medical devices. In addition, section 303 of the Medical Device User Fee and Modernization Act of 2002 directs FDA to modify the MedWatch mandatory and voluntary forms to facilitate the reporting of information by user facilities or distributors as appropriate relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

### C. Other Products Used in Medical Therapy

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements.

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
<b>CBER/CDER</b>					
Form 3500	20,074	1	20,074	0.5	10,037
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	600	463.86	278,315	1.0	278,315
<b>CDRH</b>					
Form 3500	3,252	1	3,252	0.5	1,626
Form 3500A (part 803)	1,935	33	63,623	1.0	63,623
§ 803.10	2,845	2.4	6,828	.17	1,160
<b>CFSAN</b>					
Form 3500	895	1	895	0.5	448
Form 3500A (no mandatory requirements)	0	0	0	1.0	0
<b>Total Hours</b>					<b>355,209</b>
Form 3500					13,271
Form 3500A					343,098

(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 calendar year 2002 reports and respondents for each center and type of report.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

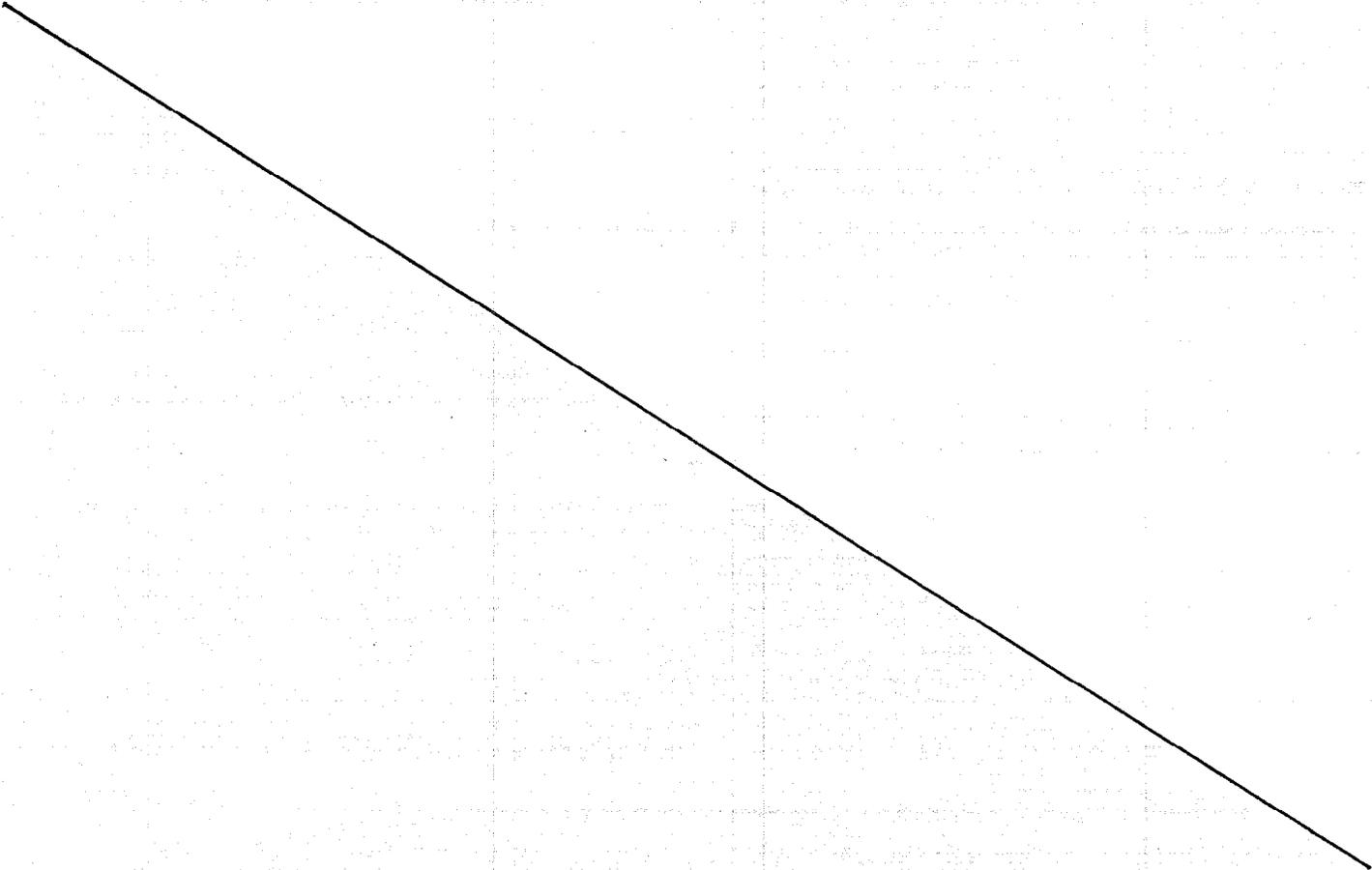
FDA Center/21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
CDRH					
803.10	2,845	2.4	6,828	.17	1,160
<b>Total</b>					<b>1,160</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of February 10, 2003 (68 FR 6752), FDA published a 60-day notice requesting public comment on the information collection provisions. Two comments from organizations (Health Industry Manufacturers Association and Baxter Healthcare Corp.) were submitted. In general, the

comments supported the reinstatement of the 3500A form with little or no modification since most manufacturers had made investments in systems that produce computer facsimiles of the form. Both organizations also questioned the need for a medical device "Baseline Report," saying that most of the information is already provided to FDA on either the 3500A form or through the Medical Device registration and listing process.

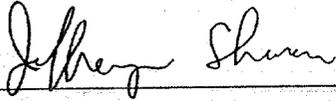
FDA recognized the impact that a major modification of the 3500A form would have on computerized systems in place across the pharmaceutical and medical device industry. In addition, the agency agreed that there is redundancy of certain data elements among the 3500A, Baseline Report and the Medical Device Registration and Listing Process. However, the agency also felt that certain elements found on the baseline form and not duplicated elsewhere were essential. At that time, experience with the use of the 3500A for mandatory medical device reporting and the need to collect information



found only on the baseline report led the agency in 1998 to propose a major modification to the medical device sections of the 3500A form.

Dated: APR 24 2003

April 24, 2003



Jeffrey Shuren  
Assistant Commissioner for Policy

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