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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0393]

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.

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 (the PRA).

DATES: Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (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 (Forms FDA 3500 and 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. 301), 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 or product problem 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 regulatory action is necessary to reduce or eliminate the public's exposure to the risk through actions 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, 312, 314, 600, and 803 (21 CFR parts 310, 312, 314, 600, and 803), specifically §§ 310.305, 312.32, 312.33, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with all medications, devices, and biologics, 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 and product problems 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, manufacturers of biologics, drugs and medical devices, distributors, and importers.

I. Use of the Voluntary Version (Form FDA 3500)

Individual health professionals are not required by law or regulation to submit adverse event or product problem reports to the agency or the manufacturer. There is one exception. The National Childhood Vaccine Injury Act of 1986 (the NCVIA) mandates that certain adverse events following the administration of vaccines specified in the NCVIA be reported by physicians to the joint FDA/Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System.

Hospitals are not required by Federal law or regulation to submit adverse event reports on medications. However, hospitals and other medical facilities are required by Federal law to report medical device-related deaths and serious 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 of 1994 puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

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

II. Use of the Mandatory Version (Form FDA 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, 312 and 314 (drugs), and part 600 (biologics). Parts 310, 314, and 600 mandate the use of the Form FDA 3500A for reporting to FDA on adverse events that occur with drugs and biologics; under § 312.32, written IND safety report notifications may be submitted on Form FDA 3500A.

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers, importers, or distributors 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 ensure that such devices are not adulterated or misbranded and to otherwise ensure its safety and effectiveness. Furthermore, 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 Form FDA 3500A for reporting to FDA on medical devices.

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. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

The agency requested comments on proposed changes to the forms which comprise this collection of information in the **Federal Register** of November 10, 1998 (63 FR 63064). FDA received 21 comments from interested parties.

Comments were made about the estimate of the "hours per response." One comment correctly stated that the "estimate may be about right for the physical act of filling out the form itself." Because Form FDA 3500A is used for mandatory reporting subject to different regulations (i.e., §§ 310.305, 312.32, 314.80, 600.80, and 803), this estimate for reporting burden is limited to completing the form. Estimates of the burden placed on user-facilities, distributors, and manufacturers to investigate a report and compile the necessary information would be addressed in the final rules for those regulations.

Comments on the mandatory version of the form generally addressed the perceived major impact such a revision would have on the pharmaceutical and medical device industry, particularly the financial burden that would result from having to both reprogram their computer systems to handle new data elements and produce printed copies of the new form. Two major reasons for not revising the form at this time were presented by multiple respondents as follows:

(1) The medical product industry (particularly the medical device industry) is focused on ensuring Year 2000 compliance. To dedicate computer personnel to totally revamp their computer systems to handle the new form would not be possible at this time because of the impact it would have on meeting absolute deadlines; and

(2) Given that the goal is for both the pharmaceutical and medical device industries to submit the majority of mandatory reports electronically, it would present a financial burden to revamp systems to accommodate a paper form that will be virtually obsolete in the future.

While the comments on the proposed revisions to the voluntary form were mainly favorable, the agency has decided to not revise either form at this time. This decision reflects both concern about the financial burden that would be placed on FDA if the voluntary form underwent revision, and the availability of other avenues by which use of the voluntary and mandatory forms can be optimized, namely appropriate revision of documents related to their completion.

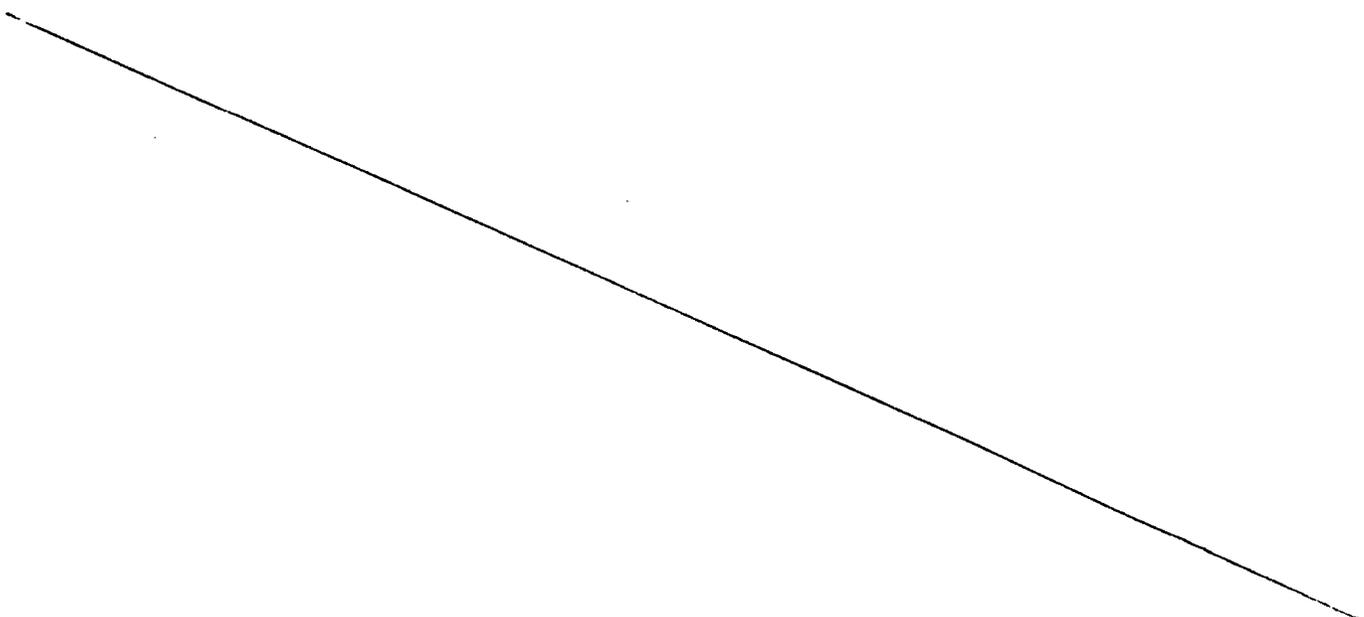
Regarding voluntary reporting, updated instructions for completing the Form FDA 3500 were posted on the Internet on the MedWatch home page in December 1998, and are available by mail/

fax upon request. Questions/comments about adverse event/product problem reporting received by the agency over time were used as a major focus for revising the instructions. This updating included such changes as incorporation of information designed to solicit information specific to special nutritional products (e.g., dietary supplements) and current Department of Health and Human Services names and definitions for race to facilitate reporting of this aspect of the medical history.

In the same vein, an omnibus entitled “Guidance on How to Complete Form FDA 3500A” for use by user facilities, distributors, importers, and manufacturers for mandatory adverse event and product problem reporting is being drafted. Also utilizing questions/comments about adverse event/product problem reporting received by the agency over time as a major focus for revision, the guidance will be designed to minimize possible ambiguity and maximize the utility of Form FDA 3500A as a tool for soliciting important safety-related information and data. It is planned that this guidance will replace instructions that are currently available.

As both the Forms FDA 3500 (instructions) and 3500A (guidance) can be updated periodically based on questions/comments from stakeholders and statutory/regulatory changes, changing the forms themselves is not seen as necessary at this point.

At such time it is decided to repropose revisions, FDA will consult all interested parties for input into the design.



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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center(s) ¹ (21 CFR Section)	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER Form 3500 ²	15,456	1	15,456	0.5	7,728
Form 3500A ³ (310.305, 312.32, 314.80, 314.98, and 600.80)	410	529.3	217,014	1	217,014
CDRH Form 3500 ²	2,789	1	2,789	0.5	1,395
Form 3500A ³ (part 803)	3,100	30.25	93,786	1	93,786
CFSAN Form 3500 ²	316	1	316	0.5	158
Form 3500A ³ (No mandatory requirements)	0	0	0	1	0
Total Hours					320,081
Form 3500 ²					9,281
Form 3500A ³					310,800

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).

² Form FDA 3500 is for voluntary reporting.

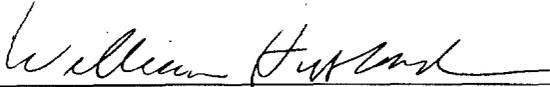
³ Form FDA 3500A is for mandatory reporting.

Note.—The figures in Table 1 of this document are based on actual calendar year 1998 reporting experience. It is assumed that the number of reports will remain stable.

The increase in reporting burden reflects a natural increase in the number of reports coming into the agency. As more medical products are approved by FDA and marketed, and as knowledge increases of the importance of notifying FDA when adverse events and product problems are

observed, it can be expected that more reports will be submitted to the agency either directly (voluntary Form FDA 3500) or via the manufacturer/user-facility (mandatory Form FDA 3500A).

Dated: September 7, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning and Legislation

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