DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0016]

Agency Information Collection Activities; Proposed Collection; MedWatch: The FDA Medical Products Reporting Program; Comment Request

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the ''MedWatch: The FDA Medical Products Reporting Program'' forms (Form FDA 3500—voluntary version and Form FDA 3500A—mandatory version). These forms are currently used to report to the agency about adverse events, product problems, and medication errors that occur with FDA regulated products, including drugs, biologicals, medical devices, and special nutritional products.

DATES: Submit written or electronic comments on the collection of information by April 11, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. Submit written comments on the collection of information to the Dockets Management Branch (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. Submit written requests for single copies of the revised MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (HFD–410), Food and Drug Administration, 5600 Fishers Lane, rm. 15B–18, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** for electronic access to the MedWatch reporting forms.

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.

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: (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, 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. 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 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/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, manufacturers of biological and drug products, medical devices, and importers.

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 (NCVIA) of 1986. Those mandatory reports are submitted by physicians to the joint FDA/Centers for Disease Control and Prevention (CDC) Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form (see *http://www.vaers.org* 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 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 drug and biologics.

[Note: Most pharmaceutical manufacturers already use a one-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 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. Furthermore, the Safe Medical Devices Act of 1990 (SMDA), 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 the FDA Form 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center (21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research/ Center for Drug Evaluation and Research					
Form 3500	20,074	1	20,074	0.5	10,037
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80)	600	463.86	278,315	1.0	278,315
Center for Devices and Radiological Health					
Form 3500	3,252	1	3,252	0.5	1,626
Form 3500A (§ 803)	1,935	33	63,623	1.0	63,623
Center for Food Safety and Applied Nutrition					
Form 3500	895	1	895	0.5	448
Form 3500A (no mandatory requirements)	0	0	0	1.0	0
Total Hours					354,049
Form 3500					12,111
Form 3500A					341,938

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

NOTE: 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 2002 reports and respondents for each Center and type of report.

IV. Electronic Access

Persons with access to the Internet may obtain the MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory) at *http://www.fda.gov/medwatch/getforms.htm* or by calling 1–800–FDA–1088 and leaving your name and mailing address. Copies of the MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory) are available for public examination at *http://www.fda.gov/ohrms/dockets/dockets/dockets.htm* or in the Dockets

Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 4, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–3174 Filed 2–7–03; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4821–N–01]

Notice of Proposed Information Collection: Comment Request; Investor and Issuer Benchmark Surveys

AGENCY: Office of the President of Government National Mortgage Association (Ginnie Mae), HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 11, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Sonya Suarez, Office of Program Operations, Department of Housing and Urban Development, 451–7th Street, SW., Room 6206, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Sonya Suarez, Ginnie Mae, (202) 708–2884 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Investor and Issuer Benchmark Surveys.

OMB *Control Number, if applicable:* N/A.

Description of the need for the information and proposed use: Ginnie Mae is currently engaged in assessing how the agency and its products are seen by current and potential issuers of and investors in secondary market securities. This proposed survey research on how Ginnie Mae and its products are perceived compared to competing entities and products in the secondary mortgage market will help Ginnie Mae improve its product offerings, services, communications and outreach to current and prospective issuers and investors in Ginnie Mae securities.

Members of affected public: For-profit business (secondary market mortgage companies and institutional investors).

Estimation of the total number of hours needed to prepare the information collection, including number of respondents, frequency of response, and hours of response: Estimates of the hour burden of collecting information for the forms are as follows:

Number of respondents	Frequency of responses	×	Total of responses	×	Hours. per response	=	Total hours
1,000	1		1,000		.25		250

Status of the proposed information collection: This is a new collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 17, 2003.

George S. Anderson,

Executive Vice President, Ginnie Mae.

[FR Doc. 03–3126 Filed 2–7–03; 8:45 am]

BILLING CODE 4210–66–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4815–N–03]

Notice of Submission of Proposed Information Collection to OMB: HOPE VI—In Depth Assessment of Family and Neighborhood Outcomes—Wave Two and Three of Panel Study

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: March 12, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577–0236) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; E-mail *Lauren_Wittenberg@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5)