The rule set forth the information to be included in a medicated feed mill license application and subsequent supplemental applications. Also, it set forth criteria for the approval and nonapproval of a medicated feed mill license application and the criteria for the revocation and/or suspension of a license. More specifically, § 515.10(b) specifies requirements for submitting a completed medicated feed mill license application, using Form FDA 3448. Section 515.11(b) specifies requirements for supplemental medicated feed applications for a change in ownership and/or change in mailing address for the facility cite, using Form FDA 3448. Section 515.23 sets forth written requirements for voluntary revocation of a medicated feed mill license by a sponsor on the grounds that the facility no longer manufacture any animal feed. Section 515.30(c) details requirements for filing a request for a hearing by a sponsor to give reasons why a medicated feed mill license application should not be refused or revoked and § 510.305(b) (21 CFR 510.305(b)) requires maintenance of approved labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

Respondents to this collection of information are individuals or firms that manufacture medicated animal feed.

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
515.10(b)	100	1	100	0.25	25
515.11(b)	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30(c)	0.15	1	0.15	24	3.6
Total					47.10

[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 per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305(b)	100	1	100	.25	25

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

The estimate for the number of respondents is derived from agency data, i.e. the number of medicated feed manufacturers entering the market each year, change in ownership or address, requests for voluntary revocation of a medicated feed mill license, revocation and/or suspension of a license. The estimate of the time required for the reporting and recordkeeping requirements is based on the agency communication with industry.

Dated: July 21, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18943 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0393]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: FDA's Medical Product 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 the ''MedWatch: The FDA Medical Products Reporting Program'' forms (Form FDA 3500 (voluntary version) and Form FDA 3500A (mandatory version). These forms will be used to report to the agency about adverse events and product problems that occur with FDA-regulated products.

DATES: Submit written comments on the collection of information by September 25, 2000.

ADDRESSES: 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 Medical Products Reporting Program (HF–2), Food and Drug Administration, 5600 Fishers Lane, rm. 17–65, Rockville, MD 20857, 301–827–7240. Send one self-addressed adhesive label to assist that office in processing your request. Copies of the forms may also be obtained via the Internet at http://www.fda.gov/medwatch under ''How to Report.''

Submit written comments on the MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), 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. Copies of

the MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory) are available for public examination via the Internet at http://www.fda.gov/ohrms/dockets/dockets/dockets.htm or in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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:

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. 301), section 402 (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 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 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, 803.50, 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.

II. 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 mandates that certain adverse reactions following immunization 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 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.

III. Use of the Mandatory version (Form FDA 3500A)

A. Drug and Biologic Products

In sections 505(j) and 704 of the act (21 U.S.C. 374), 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 Form FDA 3500A for reporting to FDA on adverse events that occur with drug and biologics.

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 dependent totally on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements. (Note: Most pharmaceutical manufacturers already use a one-page modified version of the Form FDA 3500A where section G from the back of the form is substituted for section D on the front of the form.)

D. Medical Device Baseline Information

The Medical Device Reporting—Baseline form (Form FDA 3417) relates specifically to the individual device and must be submitted with the first adverse event on that device reported via Form FDA 3500A. The information collected includes the basis for marketing (510(k), PMA, etc.), product code for the device, common name, location where manufactured, and other identifying information. The Health Industry Manufacturers Association (HIMA) first commented in 1992 on the redundancy of information required for the Baseline form stating that the information is also collected by the agency through the device listing process (Form FDA 2892) and through Form FDA 3500A. In 1998, HIMA commented again and, at the request of OMB, FDA explored revising Form FDA 3500A to include the information required by the Baseline form that is not collected through the listing process.

In discussions with OMB it was decided that FDA would not attempt to revise Form FDA 3500A at this time, but would proceed with collecting the information required by the Baseline form as a separate part of the device listing process especially because some of the information required by the current Baseline form will be collected in that listing as a change in the listing regulations. Because the collection of registration and listing information will be through electronic means, the agency envisions a menu option on the Internet site to facilitate the collection of Baseline information.

FDA will be holding stakeholder meetings to discuss the new device registration and listing system and will discuss using the new device registration and listing system electronic process as the vehicle for the Baseline information collection at those meetings.

FDA estimates the burden of 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]	16,198	1	16,198	0.5	8,099
Form 3500A [3] (310.305, 314.80, 314.98, and 600.80)	600	455.2	273,109	1.0	273,109
CDRH					
Form 3500 [2]	2,650	1	2,650	0.5	1,325
Form 3500A [3] (part 803)	2,046	24	49,305	1.0	49,305
CFSAN					
Form 3500 [2]	550	1	550	0.5	275
Form 3500A [3] (No mandatory requirements)	0	0	0	1.0	0
Total Hours					332,113
Form 3500 [2]					9,699
Form 3500A [3]					332,414

[1] CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), CFSAN (Center for Food Safety and Applied Nutrition).
[2] FDA Form 3500 is for voluntary reporting,
[3] FDA Form 3500A is for mandatory reporting.
Note.—The figures shown in table 1 of this document are based on actual calendar year 1999 reports and respondents for each Center and type of report.

As more medical products are approved by FDA and marketed, and as knowledge increases regarding the importance of notifying FDA when adverse events and product problems are observed, it is expected that more reports will be submitted.

Dated: July 21, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18944 Filed 7–25–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1373]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting and Recordkeeping Requirements for Mammography Facilities; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 17, 2000 (65 FR 44061). The document announced an opportunity for public comment on information collection requirements for mammography facilities, standards, and lay summaries for patients. The document was published with an inadvertent error. This document corrects that error.