DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1604]

Agency Information Collection Activities; Proposed Collection; Comment Request; OTC Test Sample Collection Systems for Drugs of Abuse Testing

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for over-the-counter (OTC) test sample collection systems for drugs of abuse testing.

DATES: Submit written or electronic comments on the collection of information by January 16, 2001.

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 documents should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: 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.

OTC Test Sample Collection Systems for Drugs of Abuse Testing—21 CFR Part 809 (OMB Control Number 0910–0368)—Extension

FDA has reclassified OTC test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) subject to restrictions established in accordance with section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j).

The labeling requirements for certain in vitro diagnostic products require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results. The purpose of this regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

The most likely respondents to this information collection will be manufacturers of over-the-counter drugs of abuse test kits.

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
809.10	20	1	20	100	2,000

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

Based upon submissions to the agency (premarket notifications, premarket approval applications, registration and listing), FDA estimates that there will be about 20 manufacturers of these devices.

FDA estimates, based upon discussions with manufacturers of similar devices required to comply with 21 CFR 809.10, that it will take approximately 40 hours to gather the information required by the rule, 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling as necessary.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29326 Filed 11–15–00; 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; 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.

DATES: Submit written comments on the collection of information by December 18, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, 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 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 0910–02910)—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 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. Likewise for cosmetics, the act does not give FDA the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, conduct safety testing, or report cosmetic-related injuries. Only postmarket surveillance allows FDA to assess cosmetic problems in the marketplace.

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 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, 314, 600, 606, and 803 (21 CFR parts 310, 314, 600, 606, and 803), specifically §§ 310.305, 314.80, 314.98, 600.14, 600.80, 606.170, 606.171, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with human medications, devices, and biologics, as well as any other products that are regulated by FDA, two very similar forms are used (an exception is biologic product deviation reports). 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). New biologic regulations §§ 600.14 and 606.171 require that biologic product deviation reports, which are similar to drug product problem reports, be submitted to FDA via a different form. Reports of fatalities as a complication of blood collection or transfusion are reported as per § 606.170.

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, and importers.

I. Use of the Voluntary Version (FDA Form 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 Injury Act of 1986 mandates that certain adverse events following immunization be reported by health care providers to the joint FDA/Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System (VAERS). Vaccine reporting should be submitted on Form VAERS–1 (FDA).

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, biological product deviation reports, and reports of fatalities as a complication of blood collection or transfusion.

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. Likewise for cosmetics, the act does not give FDA the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, conduct safety testing, or report cosmetic-related injuries. Only postmarket surveillance allows FDA to assess cosmetic problems in the marketplace. If a problem is detected, it is up to the agency to demonstrate that the product is harmful when used according to label directions or under customary conditions of use. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements and cosmetics.

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 (FDA Form 3500A)

A. Drug and Biologic Products

In section 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 part 600 (biologics) of the Code of Federal Regulations. Parts 310, 314, and 600 mandate the use of the FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics. Blood-related fatalities are reported per § 606.170.

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers or 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 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. FDA has codified these statutory requirements regarding mandatory reporting under part 803. Part 803 mandates the use of 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. 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. (Most pharmaceutical manufacturers already use a one-page modified version of the Form FDA 3500A where section G from the back is substituted for section D on the front of the form.)

D. Medical Device Baseline Information

The Medical Device Reporting 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 though 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 to facilitate the collection of the remainder of Baseline information.

FDA has held stakeholder meetings and discussed the new device registration and listing system and using the new device and listing system electronic process as the vehicle for the Baseline information collection at those meetings.

The agency requested comments on this proposed collection of information in the **Federal Register** of July 26, 2000 (65 FR 45988).

FDA received comments from four interested parties, but some comments raised multiple concerns.

While the comments on the proposed revisions to the form(s) were mainly favorable, the agency has decided to not revise either form at this time. This decision reflects several concerns. The financial burden that would be placed on sponsors and others required to report, and FDA if the forms 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.

One comment suggested more detailed instructions for completing the MedWatch form. The instructions for the voluntary form 3500 were updated and posted on the Internet in April 2000 and the instructions for 3500A were extensively revised and posted May 2000 (http://www.fda.gov/medwatch/report/instruc.htm). Regarding voluntary reporting, updated instructions for completing the 3500 form were posted on the MedWatch homepage in December 1998 and April 2000. They are available by mail/fax upon request. The revisions of both the voluntary and mandatory instructions for use were based on questions/comments about adverse event/product problem reporting received by the agency over time. One main revision on both forms was to include information about reporting on reuse of medical devices labeled for single use.

One comment suggested revising the March 1992 guidelines to incorporate MedWatch form use. FDA published a revised guidance for industry entitled ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report,'' in August 1997 (http://www.fda.gov/cder/guidance/1830fn1.pdf). In this guidance it states that the agency is still considering comments received in response to the proposed **Federal Register** of October 27, 1994, and recommendations recently developed by the International Conference on Harmonization and plans to propose additional amendments to its postmarketing safety reporting regulations. FDA also plans to prepare a single consolidated guidance document on this topic once the process is concluded.

One comment suggested a FDA industry-wide assessment of consistency of MedWatch field use for both devices and drugs. At this time a formal assessment of the completion of the forms is not planned. As stated above, questions/comments about use of the form and reporting have been incorporated into the revised instructions for use for both forms. This issue can also be addressed in any new proposed regulations or guidance documents.

One comment suggested expanding public education regarding postmarketing events. The MedWatch Office is in the process of developing educational materials, primarily for health professionals, to assist in the overall effort to improve the quality of MedWatch reports.

One comment was made about the estimate of the ''hours per response.'' Because the 3500A is used for mandatory reporting subject to different regulations (i.e., 21 CFR 310.305, 312.32, 314.80, 600.80, and part 803), this estimate for reporting burden is limited to completing the form. Estimates of the burden placed on user-facilities, importers and manufacturers to investigate a report and compile the necessary information would be addressed in the final rules for those regulations.

One comment suggested further clarification of the August 1997 guidance for definitions of identifiable patient and reporter. This topic is currently being discussed in the World Health Organization's Council for International Organizations of Medical Sciences, Work Group 5.

One comment suggested focusing on new or unusual events and to allow reporting of known non-serious events via line listing. This same commenter suggested minimal data collection for known and well-characterized cases. These comments are addressed in the August 1997 guidance for industry entitled ''Postmarketing Adverse

Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report.''

One comment suggested adding a box to the 3500A form to require drug manufacturers to state the date the report was forwarded to FDA. This is currently required for medical device reporting, but not for drugs and biologics. However, all manufacturers must report the date received by the manufacturer on form 3500A, section G4. Many large manufacturers have data bases that contain the date the information was received and the date the report was sent to FDA. As a surrogate, these two dates can be compared to see if the company is fulfilling its requirements under the regulations. The agency can use its regulatory discretion in deciding whether or not action is warranted in the case of delayed reports. What is of greater concern is the failure to report and that cannot be detected by adding this information to the form. Given that the goal is for both 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.

One comment suggested a ''tick box for a 30-day report,'' for form 3500A. At this time there is no requirement for a 30-day report.

As both the 3500 instructions and 3500A instructions 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 [1]

FDA center(s) (21 CFR section)	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CBER/CDER[2]					
Form 3500	16,198	1	16,198	0.5	8,099
Form 3500A (310.305, 314.80, 314.98, and 600.80)	600	455.2	273,109	1	273,109
CDRH[3]					
Form 3500	2,650	1	2,650	0.5	1,325
Form 3500A (part 803)	2,046	24	49,305	1	49,305
CFSAN[4]					
Form 3500	550	1	550	0.5	275
Form 3500A	0	0	0	1	0
No mandatory requirements					
Total Hours					332,113
Form 3500					9,699
Form 3500A					322,414

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research.
[3] Center for Devices and Radiological Health.
[4] 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 1999 reports and respondents.

As more medical products are approved by the 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 voluntary reports will be submitted. Conversely, with the current plans for increasing electronic submissions it is expected that the number of mandatory reports will decrease.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29324 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1435]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

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.

DATES: Submit written comments on the collection of information by December 18, 2000.

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

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.