

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N-0051]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Adverse Event Pilot Program for Medical Devices and Blood Products

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 or electronic comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. 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: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

Adverse Event Pilot Program for Medical Devices and Blood Products

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA) amended section 519(b) of the act relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment required FDA to, by regulation, replace universal user-facility reporting with a system that is limited to a “* * * subset of user facilities that constitutes a representative profile of user reports” for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act.

FDA is the Federal agency charged with the responsibility for ensuring that marketed medical products are safe and effective. 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 it 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 this risk. Data collected from user facilities about problems with medical devices assist FDA to carry out that mission as it pertains to medical devices. Prior to implementing the regulation to change from universal user-facility reporting to reporting by a subset of user facilities, FDA is planning to conduct a pilot program to evaluate various aspects of the new program. The new user-facility program that will be comprised of a subset of user facilities is called the Medical Product Surveillance Network (MedSuN). Two FDA Centers, the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) are participating in this project. Data collected from the pilot will aid FDA in fulfilling its mission to monitor the safety and effectiveness of marketed medical devices as they are used in clinical settings and to determine what aspects of the pilot program should be implemented in the national program. The current FDA universal

user-facility reporting system remains in place during the piloting of the new program, and will remain until FDA implements the new MedSuN national system by regulation.

An electronic format of the medical device related sections of the mandatory MedWATCH form (form 3500A; OMB Control number 0910-0291) will be accessible to the participating medical device user facilities and the participating blood establishments. The facilities participating in the collection of medical device-related adverse events will use this electronic format in reporting to FDA. The electronic format will include some additional items that are not on the 3500A form. These will be voluntary for participants to complete, such as hospital profile information and several questions related to the use of medical devices.

During this pilot project, FDA is planning to include the electronic collection of voluntary information related to blood products. Currently blood establishments and transfusion centers must investigate and keep records of adverse events regarding blood or blood products arising as a result of blood collection or transfusion (§ 606.170(a) (21 CFR 606.170(a))). In addition, when the event is fatal, FDA must be notified immediately (by telephone, facsimile, express mail, or e-mail) and a written report must be submitted within 7 days of the transfusion (§ 606.170(b)). Deviations in the manufacturing of biological products, including blood and blood components, according to the recently published rule entitled "Biological Products: Reporting of Biological Product Deviations in Manufacturing" (November 7, 2000, 65 FR 66621), must also be reported to FDA when the product is distributed (21 CFR 606.171). The form for these reports is pending OMB approval.

However, these mandatory reports do not include errors related to the use of the product and do not include "near-miss" errors, an important way of analyzing weaknesses in the systems. The "Medical Event Reporting System for Transfusion Medicine" (MERS-TM) has been designed to provide this type of information. For this pilot program, blood transfusion centers and blood establishment centers who currently use the MERS-TM to track internal events will be recruited to participate. These facilities will be asked to fill in the textual description of the blood product-

related adverse event and to transfer the two outcome codes from the MERS-TM concerning problems with blood products to two additional data fields in the electronic format that will be dedicated to collecting this coded information. FDA will compare the information obtained in this reporting system with that obtained under existing mandatory and voluntary systems that are in place for transfusion-related fatalities, product deviations, and clinical adverse events. FDA will consider the information that is voluntarily reported under this pilot program to design a system that will assist FDA in gathering the most useful data, in the least burdensome manner, for its regulation (including packaging and labeling provisions) of establishments and products used in transfusion medicine.

Participation in this pilot will be voluntary and will initially include 25 hospitals that will respond to the medical device questions. At the same time, an initial 9 blood establishments and transfusion services sites, which currently use the MERS-TM, will be recruited to participate. It is anticipated that during this pilot the number of participants will increase to approximately 250 facilities reporting medical device problems and the number of blood establishments and transfusion-services sites is anticipated to increase to 30. The electronic version will take approximately 45 minutes, or less, to complete. For the blood centers that are participating, the burden of participation will be approximately 15 minutes.

In the **Federal Register** of February 8, 2001 (66 FR 9580), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

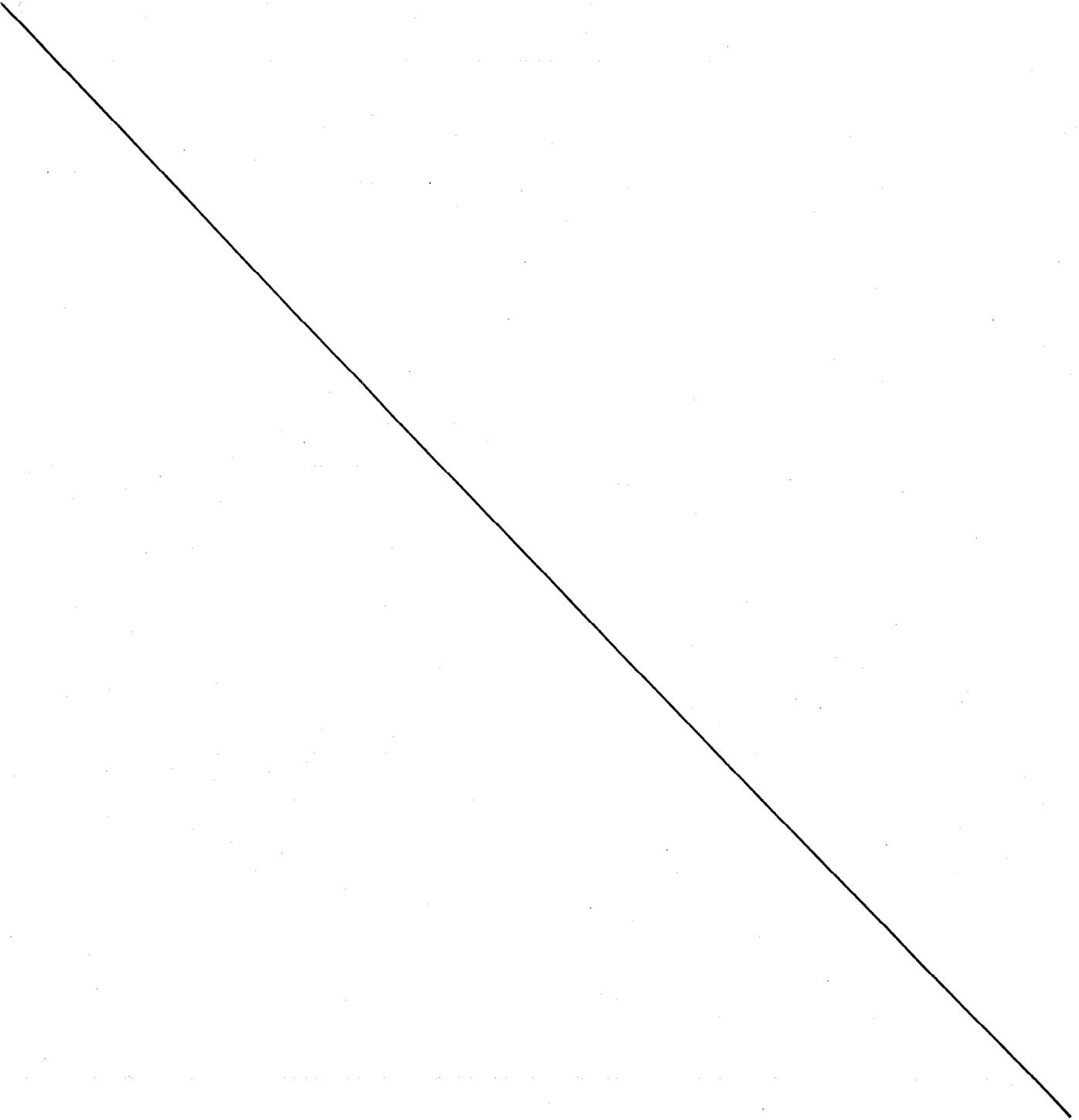
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Medical devices: 83	15	1,245	.75	934
Blood transfusions: 10	150	1,500	.25	375
Total				1,309

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

The number of respondents for medical devices was determined by the average number of respondents given that 25 facilities will be enrolled in the first year, up to 100 the second year,

and up to 250 the third year. Eighty-three is the average of the final complement of 250 facilities. The annual frequency of response is based on FDA's experience with its mandatory and voluntary reporting systems.

The number of respondents for blood transfusions was determined by the average number of respondents given that a total of 30 blood establishments will be enrolled at the end of 3 years.



The annual frequency of response was based on the information that the American Red Cross submits about 15 reports per establishment per year. The MERS-TM will yield about a tenfold higher than the American Red Cross rate since it will include close calls as well as actual adverse events.

Dated: 5/18/01
May 18, 2001.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Kamoni Oliver

Margaret M. Dotzel
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Associate Commissioner for Policy.

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