ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Interim Tribal TANF Data Report	18	4	451	32,472

Estimated Total Annual Burden Hours: 32,472.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Lori Schack.

Dated: February 8, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–3475 Filed 2–11–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0364]

Agency Information Collection Activities; Announcement of OMB Approval; Recordkeeping for Electronic Products, Specific Product Requirements; 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 January 5, 1999 (64 FR 516). The document announced that a collection of information entitled ''Reporting and Recordkeeping for Electronic Products: Specific Product Requirements'' has been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The document was inadvertently published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Silvia R. Fasce, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

In FR Doc. 99–71, appearing on page 516 in the **Federal Register** of Tuesday, January 5, 1999, the following correction is made:

On page 516, in the first column, ''[Docket No. 98N–0213]'' is corrected to read ''[Docket No. 98N–0364]''.

Dated: February 5, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3438 Filed 2–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0132]

FDA Modernization Act of 1997: Guidance on Medical Device Tracking; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised final guidance entitled ''Guidance on Medical Device Tracking.'' It replaces the previous final guidance issued on March 4, 1998. This revised final guidance provides guidelines to manufacturers and distributors concerning their responsibilities for medical device tracking under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the revised final guidance entitled ''Guidance on Medical Device Tracking'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on ''Guidance on Medical Device Tracking'' to the contact person (address below). See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Background

Section 211 of FDAMA (Pub. L. 105–115) amended the tracking provisions of section 519(e) of the act (21 U.S.C. 360i(e)) to authorize FDA, at its discretion, to issue orders that require a manufacturer to track a class II or class III device if the failure of the device would be reasonably likely to have serious adverse health consequences, or the device is intended to be implanted in the human body for more than 1 year, or is life sustaining or life supporting and used outside a device user facility. The FDAMA tracking provisions became effective on February 19, 1998.

On January 15, 1998, FDA conducted a public meeting to discuss FDAMA changes in section 519(e) of the act. Comments were received concerning factors FDA should consider in determining what devices are subject to FDAMA tracking requirements. On February 11, 1998, FDA issued tracking orders, under the revised FDAMA tracking provisions which became effective on February 19, 1998, to manufacturers of devices that were subject to tracking previously under the Safe Medical Devices Act of 1990 (the SMDA) provisions (21 CFR 821.20(b)(1), (b)(2), and (c)). Additionally, tracking orders were issued to manufacturers of intraocular lenses and arterial stents that had not been subject to tracking under the SMDA provisions (63 FR