

CDC Procurement and Grants Office,  
2920 Brandywine Road, Atlanta, GA  
30341-4146. Telephone: 770-488-2700.

For technical questions about this program, contact: David M. Allen, M.D., M.P.H., CDC Global AIDS Program, U.S. Embassy, P.O. Box 9536, Pretoria, South Africa 0001, Telephone: 27 12 346 0170, E-mail: [allend@sacdc.co.za](mailto:allend@sacdc.co.za).

Dated: March 11, 2003.

**Sandra R. Manning,**

*Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention.*

[FR Doc. 03-6264 Filed 3-14-03; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

*Name:* CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment.

*Times and Dates:* 8:30 a.m.—5 p.m., May 15, 2003.

8:30 a.m.—12 p.m., May 16, 2003.

*Place:* Sheraton Colony Square Mid-Town, 188 14th Street at Peachtree, Atlanta, Georgia 30361

*Status:* Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

*Purpose:* This Committee is charged with advising the Secretary, HHS, the Director, CDC, and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS and other STDs. The Committee will support the Agencies' process of identifying and responding to the prevention and health service delivery needs of affected communities, and the needs of individuals living with or at risk for HIV and other STDs.

*Matters To Be Discussed:* Agenda items include issues pertaining to (1) HIV and STD prevention for Men Who Have Sex With Men (MSM) (2) AIDS Drug Assistance Program (ADAP) and (3) CARE ACT Reauthorization. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Paulette Ford-Knights, Public Health Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E-07, Atlanta, Georgia 30333. Telephone 404/639-8008, fax 404/639-3125, e-mail [pbj7@cdc.gov](mailto:pbj7@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the

authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 10, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03-6266 Filed 3-14-03; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 02N-0496]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition**

**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 (the PRA).

**DATES:** Fax written comments on the information collection provisions by April 16, 2003.

**ADDRESSES:** Fax written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202-395-6974, or electronically mail comments to [sshapiro@omb.eop.gov](mailto:sshapiro@omb.eop.gov).

**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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition—21 CFR 201.323 (OMB Control Number 0910-0439)—Extension**

FDA is requesting OMB approval under the PRA (44 U.S.C. 3501—3520) for the labeling requirements for

aluminum content in large volume parenterals (LVPs), small volume parenterals (SVPs), and pharmacy bulk packages (PBPs) used in total parenteral nutrition (TPN). As explained in the final rule on aluminum content labeling requirements published in the **Federal Register** of January 26, 2000 (65 FR 4103), aluminum content in parenteral drug products could result in a toxic accumulation of aluminum in the tissues of individuals receiving TPN therapy. Research indicates that neonates and patient populations with impaired kidney function may be at high risk of exposure to unsafe amounts of aluminum. Studies show that aluminum may accumulate in the bone, urine, and plasma of infants receiving TPN. Many drug products used routinely in parenteral therapy may contain levels of aluminum sufficiently high to cause clinical manifestations. Generally, when medication and nutrition are administered orally, the gastrointestinal tract acts as an efficient barrier to the absorption of aluminum, and relatively little ingested aluminum actually reaches body tissues. However, parenterally administered drug products containing aluminum bypass the protective mechanism of the gastrointestinal tract and aluminum circulates and is deposited in human tissues.

Aluminum toxicity is difficult to identify in infants because few reliable techniques are available to evaluate bone metabolism in premature infants. Techniques used to evaluate the effects of aluminum on bone in adults cannot be used in premature infants. Although aluminum toxicity is not commonly detected clinically, it can be serious in selected patient populations, such as neonates, and may be more common than is recognized.

FDA amended its regulations to add labeling requirements for aluminum content in LVPs, SVPs, and PBPs used in TPN. FDA specified an upper limit of aluminum permitted in LVPs and required applicants to submit to FDA validated assay methods for determining aluminum content in parenteral drug products. The agency added these requirements because of evidence linking the use of parenteral drug products containing aluminum to morbidity and mortality among patients on TPN therapy, especially among premature neonates and patients with impaired kidney function.

The information collection reporting requirements resulting from this rulemaking are as follows:

21 CFR 201.323(b)—Requires that the package insert of all LVPs used in TPN therapy state that the drug product

contains no more than 25 micrograms per liter (µg/L). This information must be contained in the "Precautions" section of the labeling of all LVPs used in TPN therapy.

21 CFR 201.323(c)—Requires that the maximum level of aluminum present at expiry be stated on the immediate container label of all SVP drug products and PBPs used in the preparation of TPN solutions. The aluminum content must be stated as prescribed in the regulation. The immediate container label of all SVP drug products and PBPs that are lyophilized powders used in the preparation of TPN solutions must contain the statement prescribed in the regulation.

21 CFR 201.323(d)—Requires that the package insert for all LVPs, SVPs, and PBPs used in TPN contain a warning statement, prescribed in the regulation, intended for patients with impaired kidney function and for neonates

receiving TPN therapy. This information must be contained in the "Warnings" section of the labeling.

21 CFR 201.323(e)—Requires that applicants and manufacturers must use validated assay methods to determine the aluminum content in parenteral drug products. The assay methods must comply with current good manufacturing practice requirements. Applicants must submit to FDA both validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections. Holders of pending applications must submit an amendment to the application.

Compliance with the information collection burdens under §201.323(b), (c), and (d) (21 CFR 201.323(b), (c), and (d)) consists of submitting application

supplements to FDA containing the revised labeling for each product. Based on data concerning the number of applications for LVPs, SVPs, and PBPs used in TPN received by the agency, FDA estimates that the labeling for approximately 200 products will be changed under §201.323(b), (c), and (d). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each labeling change. FDA estimates that approximately 65 respondents will each submit 1 validated assay method annually under §201.323(e). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each validated assay.

In the **Federal Register** of December 19, 2002 (67 FR 77792), the agency requested comments on the proposed collection of information. No comments were received.

The burdens can be charted as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.323(b),(c),(d)	200	1	200	14	2,800
201.323(e)	65	1	65	14	910
Total					3,710

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

Dated: March 10, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-6227 Filed 3-14-03; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 03N-0085]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations**

**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 information collection contained in FDA regulations entitled "Environmental Impact Considerations."

**DATES:** Submit written or electric comments on the collection of information by May 16, 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.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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;