TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (Includes Screening)	Total Hours
Total		28	286		1.78	4,252

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

Dated: February 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–2726 Filed 2–24–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0080]

Agency Information Collection Activities; Proposed Collection; 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 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 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).

DATES: Submit written or electronic comments on the collection of information by April 28, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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 Management Programs (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 these topics: (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.

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 for the labeling requirements for aluminum content in LVPs, SVPs, and PBPs used in TPN. As explained in the final rule on aluminum content labeling requirements published in the **Federal Register** of January 26, 2000 (65 FR 4103) (the January 2000, final rule), 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 are as follows:

Section 201.323(b) (21 CFR 201.323(b)) requires that the package insert of all large volume parenterals used in total parenteral nutrition therapy state that the drug product contains no more than 25 micrograms (µg)/liter (L). This information must be contained in the ''Precautions'' section of the labeling of all LVPs used in TPN therapy.

Section 201.323(c) (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.

Section 201.323(d) (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.

Section 201.323(e) (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) consists of submitting application supplements to FDA containing the revised labeling for each product, and analytical method validation must be submitted under § 201.323(e). During the period since the publication of the January 2000, final rule, FDA has received approximately 100 supplements and analytical method validation from approximately four respondents. Because the final rule was effective on July 26, 2004, FDA expects to receive fewer submissions per year. FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each submission.

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
201.323(b),(c),(d)	4	1.25	5	14	70
201.323(e)	4	1.25	5	14	70
Total					140

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

Dated: February 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Open Meeting of the Federal Interagency Committee on Emergency Medical Services (FICEMS)

AGENCY: Federal Emergency Management Agency (FEMA), Department of Homeland Security.

ACTION: Notice of open meeting.

SUMMARY: FEMA announces the following open meeting.

Name: Federal Interagency Committee on Emergency Medical Services (FICEMS).

Date of Meeting: March 2, 2006.

Place: 10th Floor MacCracken Room, FAA Building, 800 Independence Ave SW., Washington, DC 20591.

Times: 10:30 a.m.—Main FICEMS Meeting; 1 p.m.—FICEMS Ambulance Safety Subcommittee.

Proposed Agenda: Review and submission for approval of previous FICEMS Committee Meeting Minutes; Ambulance Safety Subcommittee Meeting Minutes; Action Items review; presentation of member agency reports; and reports of other interested parties.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public with limited seating available on a first-come, first-served basis. See the Response and Security Procedures below.

Response Procedures: Committee Members and members of the general public who plan to attend the meeting should contact Mr. Mike McKay, on or before Tuesday, February 28, 2006, via mail at NATEK Incorporated, 21355 Ridgetop Circle, Suite 200, Dulles, Virginia 20166–8503, or by telephone at (703) 674–0190, or via facsimile at (703) 674–0195, or via e-mail at *mmckay@natekinc.com.* This is necessary to be able to create and provide a current roster of visitors to FAA Security per directives.

Security Procedures: All visitors must have a valid picture identification card and their vehicles will be subject to search by Security personnel. All visitors will be issued a visitor pass which must be worn at all times while in the facility. Please allow adequate time before the meeting to complete the security process.

Conference Call Capabilities: If you are not able to attend in person, a toll free number has been set up for teleconferencing. The toll free number will be available from 10 a.m. until 4 p.m. Members should call in around 10:30 a.m. The number is 1–800–320–4330. The FICEMS conference code is ''361352#,'' which is different.

FICEMS Meeting Minutes: Minutes of the meeting will be prepared and will be available upon request 30 days after they have been approved at the next