Dated: February 21, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0443]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 29, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Focus Groups as Used by the Food and Drug Administration—(OMB Control Number 0910–0497)—Extension

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

In the **Federal Register** of November 25, 2005 (FR 70 71165), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment, however it was not related to the information collection.

Annually, FDA projects about 28 focus group studies using 286 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs. To arrive at each center's estimated burden we multiplied the number of focus groups per study by the number of participants per group. (*e.g.,* Center for Biologics Evaluation and Research (CBER): 5x9=45). We multiplied that total by the hours of duration for each group to arrive at the total burden hours. (*e.g.,* CBER: 45x1.58=71.1).

The total annual estimated burden imposed by this collection of information is 4,252 hours annually.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (*e.g.,* direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication)	10	200	9	1.58	2,844
Center for Devices and Radiological Health	Varies (*e.g.,* FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves)	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (*e.g.,* food safety, nutrition, dietary supplements, and consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (*e.g.,* animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468

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