effectiveness of these products, and (c) practical utility of these products.

The reader evaluation surveys provide important feedback that enables ATSDR staff to maintain the utility, integrity and standards of its products. Gathering client feedback ensures that appropriate information is included in these documents and assists in maintaining medical and scientific usefulness. The information will be used to maintain customer satisfaction with these products. There is no cost to respondents.

Respondents	Number of respondents	Responses/ respondent	Average burden/response (in hours)	Total burden (in hours)
Community member reviewing public health assessments	130	1	15/60	32.5
Environmental regulatory official requesting health consultations	210	1	15/60	52.5
Community member requesting health consultations	50	1	15/60	12.5
Community member reviewing public health fact sheets	750	1	15/60	187.5
Total				285

Dated: November 27, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–31926 Filed 12–18–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10078]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with the Trade Act of 2002. We cannot reasonably comply with the normal clearance procedures because of an unanticipated event and public harm.

President Bush signed into law on August 6, 2002, the Trade Act of 2002. Additionally, the law provided funding of $20 million in Fiscal Year (FY) 2003 for seed grants to states to create high risk insurance pools and $80 million ($40 million in FY 2003 and $40 million in FY 2004) for matching grants to states for the operation of existing high risk pools. The provision in the legislation about high risk pools was unanticipated. (High risk pools are a mechanism for states to provide health coverage to individuals who cannot obtain health insurance in the private market because of a history of illnesses.)

In addition, public harm will result if funding to the states is delayed in any manner. The purpose of the grant program is to provide money to the states to expand the coverage in the high risk pools to make it available to more individuals. Any delay in the funding, therefore, would result in a delay in individuals obtaining health care for their illnesses. Because of this, the Bush Administration has instructed that this program to be enacted as quickly as possible.

CMS is requesting OMB review and approval of this collection by January 3, 2003, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by January 2, 2003. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection; *Title of Information Collection:* Matching Grants to States for the Operation of High Risk Pools; *Form No.:* CMS–10078 (OMB# 0938–XXXX); *Use:* HHS/CMS is requiring this information as a condition of eligibility for grants that were authorized in the Trade Act of 2002 (Pub. L. 107–210). The information is necessary to determine if a state applicant meets the necessary eligibility criteria for a grant as required by the law. The respondents will be states that have a high risk pool as defined in section 2744(c)(2) of the Public Health Service Act. The grants will provide matching funds to states that incur losses in the operation of high risk pools. High risk pools are set up by states to provide heatlh insurance to individuals that cannot obtain health insurance in the private market because of a history of illness; *Frequency:* On occasion; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 800.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp* or E-mail

your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by December 30, 2002.

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–3064. Attn: Julie Brown.

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167. Attn: Brenda Aguilar, CMS Desk Officer.

Dated: December 10, 2002.

John P. Burke, III,

CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 02–31923 Filed 12–18–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0496]

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 parental nutrition (TPN).

DATES: Submit written or electronic comments on the collection of information by February 18, 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 L. 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; (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), 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