

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 LVPs used in TPN 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.

In the **Federal Register** of February 27, 2006 (71 FR 9829), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 201.323(b), (c), and (d) | 4 | 1.25 | 5 | 14 | 70 |
| 201.323(e) | 4 | 1.25 | 5 | 14 | 70 |
| Total | | | | | 140 |

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

Dated: May 18, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0203]

Agency Information Collection Activities; Proposed Collection; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 User Fee Cover Sheet; Form FDA 3397 that must be submitted along with

certain drug and biologic product applications and supplements.

DATES: Submit written or electronic comments on the collection of information by July 24, 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: Jonna Capezuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910-0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102-571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 107-188), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to FDA for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee

required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2005, there are an estimated 243 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions, and some may have multiple submissions in a given year. The total number of annual responses is based on the number of submissions received by FDA in FY 2005. CDER estimates 3,085 annual responses that include the following submissions: 101 new drug applications; 3 biologics license applications; 1,915 manufacturing supplements; 921 labeling supplements; and 145 efficacy supplements. CBER estimates 676 annual responses that include the following submissions: 6 biologics license applications, 614 manufacturing supplements, 46 labeling supplements, and 10 efficacy supplements. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Form | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| FDA 3397 | 243 | 15.48 | 3,761 | 0.30 | 1,128 |

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

Dated: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0296]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Financial Disclosure by Clinical Investigators" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 10, 2006 (71 FR 7051), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0396. The

approval expires on April 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0500]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Health Care Facilities—Survey

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 June 26, 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: Karen Nelson, Office of Management Programs (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.

Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Healthcare Facilities—Survey (OMB Control Number 0910-0548)—Extension

FDA has received four reports of medical gas mixups occurring during the past 7 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mixups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mixups and to determine if further steps are warranted to ensure the safety of patients.

In the **Federal Register** of January 3, 2006 (71 FR 122), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 210 and 211 | 285 | 1 | 285 | .25 | 71.25 |
| Total | 285 | 1 | 285 | .25 | 71.25 |

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