

collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: Katherine_T._Astrich@omb.eop.gov.

Dated: November 16, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05-23084 Filed 11-21-05; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Invitation to Comment on Proposed Data Composites and Potential Performance Areas and Measures for the Child and Family Services Review

AGENCY: Children's Bureau (CB), Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), Department of Health and Human Services.

ACTION: Correction notice to the following action: Invitation to comment on proposed data composites and potential performance areas and measures for the Federal Child and Family Services Review (CFSR).

Corrective Action: The initial publication in the **Federal Register** on November 7, 2005 (70 FR 67479) inadvertently omitted the date that the comments are due to the Children's Bureau. The due date for comments is December 7, 2005.

Dated: November 17, 2005.

Reginia H. Ryan,

Director, Executive Secretariat, ACYF.

[FR Doc. 05-23206 Filed 11-21-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0153]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Regulations For In Vivo Radiopharmaceuticals Used For Diagnosis and Monitoring" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of May 3, 2005 (70 FR 22887), 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 0910-0409. The approval expires on October 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 15, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-23039 Filed 11-21-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0343]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

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 proposed collection of information associated with the guidance document entitled "Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006." Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the Office of Management and Budget (OMB's) approval of this collection of information (OMB control number 0910-0571). Since this was an emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information by January 23, 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:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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.

Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006 (OMB Control Number 0910–0571)—Extension

This policy provides guidance to FDA and the food industry about when and how businesses may request the agency to consider enforcement discretion for the use of some or all existing label stock, that does not declare *trans* fat labeling in compliance with the final rule, on products introduced into interstate commerce on or after the January 1, 2006, effective date. **Industry Compliance With the *Trans* Fat Final Rule**

FDA issued a final rule (the *trans* fat final rule) on July 11, 2003, (68 FR 41434) to require food labels to bear the gram (g) amount of *trans* fat without a percent Daily Value (% DV) directly under the saturated fat line on the Nutrition Facts panel (<http://www.cfsan.fda.gov/~acrobat/fr03711a.pdf>). The *trans* fat final rule affects almost all manufacturers of packaged, labeled food sold in the United States. FDA believes that most businesses, including small businesses, should not have difficulty meeting the January 1, 2006, effective date of the *trans* fat final rule. However, under certain circumstances some businesses may want to request that the agency consider an extension of time to use current labels that are not in compliance with the *trans* fat final rule. Therefore, the agency believes that it would be

appropriate to consider, on a case-by-case basis, whether to exercise enforcement discretion on the January 1, 2006, effective date for *trans* fat labeling for some businesses that can make an appropriate showing.

The agency intends to consider the following factors in any request from a firm for the agency’s exercise of enforcement discretion:

- Whether products contain 0.5 g or less *trans*fat;
- The explanation of why the request is being made;
- The number of existing labels that the firm is requesting to use;
- The dollar amount associated with the number of existing labels to be used; and
- The estimate of the amount of time needed, not exceeding 12 months, to exhaust the number of existing labels the firm is requesting to use.

Requests may be considered at any time before or after the January 1, 2006, effective date of the *trans* fat final rule. Firms may submit their requests in writing to FDA’s Center for Food Safety and Applied Nutrition. Firms are encouraged to keep this letter of request for their records and should make a copy available for inspection to any FDA officer or employee of who requests it. FDA intends to use the information in the letter to make decisions about whether a firm’s product is subject to FDA’s enforcement discretion for the *trans* fat labeling requirements.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written requests to FDA in year one	56	1	56	5	280
Written requests to FDA in year two	28	1	28	5	140
Onetime burden hours for years one and two					420

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

FDA estimates a 2-year time period during which these requests will be made following the issuance of this guidance. Beyond 2 years, FDA expects businesses to fully comply with the *trans* fat final rule, as it is unlikely that there will still be old labeling stock left to use.

FDA expects that, although all sizes of business are eligible, small businesses and very small businesses are the firms most likely to be able to demonstrate a need to request an extension to the *trans* fat labeling deadline. The agency has

already received three requests from businesses regarding the *trans* fat labeling compliance date of January 1, 2006. Because small businesses are more likely to submit requests for extensions, and most of the affected businesses are small, we use the number of small businesses as the base to calculate the reporting burden. The regulatory flexibility analysis of the *trans* fat final rule estimated that 11,180 small businesses will have to revise the labels on their products as a result of the *trans* fat final rule. Given that only three

businesses have submitted requests to FDA so far, FDA estimates that, in the first year following the issuance of the guidance, the total number of businesses that will request a labeling compliance extension from FDA can be estimated as approximately 0.5 percent of the number of small businesses, which equals 56.

FDA estimates that it will take one employee approximately 4 hours to put together a request to FDA and approximately 1 hour for a supervisor to look over the request before submitting

it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-23040 Filed 11-21-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0343]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing an opportunity for public comment on this collection of information. Since this collection received emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing that notice.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2005 (70 FR 52108), 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 0910-0571. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-23041 Filed 11-21-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 12, 2005, 9 a.m.—5 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Monday, December 12, from 9 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1-800-369-6048 on December 12 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the December meeting will include, but are not limited to: A summary of the U.S. Court of Federal Claims' 18th Judicial Conference; a report from the ACCV Workgroup looking at proposed guidelines for future changes to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services

Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail clee@hrsa.gov. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-2124 or e-mail clee@hrsa.gov.

Dated: November 15, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-23042 Filed 11-21-05; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing patient assistance programs for Medicare Part D enrollees.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619-0335.

SUPPLEMENTARY INFORMATION:

Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (November 2005)

I. Introduction

Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means