

I.D. and sign-in at the security desk upon entering the building.

Because of increased security requirements, those who wish to attend a specific ICD-9-CM C&M meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the December 4-5, 2003 meeting must submit their name and organization by November 28, 2003 for inclusion on the visitor list.

This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting. Those who attended previous ICD-9-CM C&M meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend.

Send your name and organization to one of the following by November 28, 2003 in order to attend the December 4-5, 2003 meeting: Pat Brooks pbrooks1@cms.hhs.gov (410) 786-5318. Ann Fagan afagan@cms.hhs.gov (410) 786-5662. Amy Gruber agruber@cms.hhs.gov (410) 786-1542.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room, the meeting will be closed.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 10, 2003.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03-26272 Filed 10-16-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities (PCPID); Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID); Department of Health and Human Services.

ACTION: Corrected notice of meeting.

SUMMARY: This document clarifies and corrects the notice that was published in the **Federal Register** on October 9, 2003 (68 FR 58352). It corrects a statement that a portion of the meeting would be closed to the public. The full Committee meeting of the President's Committee for People with Intellectual Disabilities will be open to the public pursuant to section 10(a)(1) of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Subcommittees of the Committee will have breakout working sessions from 1:30 p.m. to 4 p.m. for the purpose of preliminary discussions on issues of the PCPID. This notice is filed less than 15 calendar days prior to the meeting date due to scheduling conflicts.

FOR FURTHER INFORMATION CONTACT:

Sally Atwater, Executive Director, President's Committee for People with Intellectual Disabilities. Aerospace Center Building, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone (202) 619-0634, Fax (202) 205-9519, E-mail: satwater@acf.hhs.gov.

Dated: October 9, 2003.

Sally Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. 03-26277 Filed 10-16-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0463]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

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 information collection regarding the manufacture of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

DATES: Submit written or electronic comments on the collection of information by December 16, 2003.

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 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.

Infant Formula Requirements—21 CFR Parts 106 and 107 (OMB Control Number 0910-0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA

when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in 21 CFR part 106 and part 107 (21 CFR part 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an

infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. In a notice of proposed rulemaking published in the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this

document. The document included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses ²	Hours per Response	Total Hours
Section 412(d) of the act	4	13	52	10	520
106.120(b)	4	0.25	1	4	4
107.10(a) and 107.20	4	13	52	8	416
107.50(b)(3) and (b)(4)	3	2	6	4	24
107.50(e)(2)	3	0.33	1	4	4
Total					968

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

²Manufacturers may submit infant formula notifications in electronic format.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
106.100	4	10	40	4,000	160,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					250,000

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

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-26284 Filed 10-16-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003F-0471]

T&R Chemicals, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that T&R Chemicals, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of glycerol ester of gum rosin to adjust the density of citrus oils used in the preparation of beverages.

FOR FURTHER INFORMATION CONTACT: Clarence W. Murray, III, Center for Food Safety and Applied Nutrition (HFS-

265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3601.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409 (b)(5) (21 U.S.C. 348(b)(5))) notice is given that a food additive petition (FAP 3A4749) has been filed by T&R Chemicals, Inc., c/o The Environ Health Sciences Institute, 4350 N. Fairfax Dr., suite 300, Arlington, VA 22203. The petition proposes to amend the food additive regulations in Part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of glycerol ester of gum rosin to adjust the density of citrus oils used in the preparation of beverages. The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,