

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.

² Manufacturers 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.

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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,