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 BURDEN[1]

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

[1]There 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 BURDEN[1]

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

[1]There 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,

neither an environmental assessment nor an environmental impact statement is required.

Dated: September 25, 2003.

Laura M. Tarantino,

Deputy Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03–26267 Filed 10–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the National Center for Food Safety and Technology; Notice of Intent to Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), announces its intent to award on an urgent basis, a single-source, program expansion supplement to the current cooperative agreement with the Illinois Institute of Technology (IIT) for $1.1 million in fiscal year (FY) 2004. This cooperative agreement provides support for the National Center for Food Safety and Technology (NCFST), which is located on IIT's Moffett Campus in Summit-Argo, IL. The additional funding will enable IIT to undertake two new food contaminant mitigation projects and to continue the build-out of the biosafety level 3 (BSL–3) laboratory that began last year.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Maura Stephanos, Division of Contracts and Grants Management (HFA–531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183, e-mail: *mstepha1@oc.fda.gov*.

Regarding the programmatic aspects: Karen Carson, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1664, e-mail: *kcarson@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Restricted Eligibility

Assistance will be provided to IIT for the following reasons:

1. As part of FDA's food safety and security program, development of effective mitigation strategies requires a better understanding of food processing techniques that could be used to reduce the likelihood that contaminants persist in food following processing. This type of research requires expertise in food processing and packaging in addition to the availability of facilities and equipment appropriate to this type of research. The IIT/NCSFT has these resources. Additionally, IIT/NCSFT has available through this collaborative research program, the scientific and practical experience in a wide variety of food commodities and processing techniques that will feed into the development of mitigation strategies. This research will build on the ongoing food safety research program.

2. Last fiscal year FDA provided funds to IIT to expand the existing BSL–3 pilot plant facility to include BSL–3 laboratories. This is the only BSL–3 food processing pilot plant to which FDA has ready access. Expansion of the BSL–3 pilot plant facility will provide critical support to the overall research and will provide the flexibility to have more than one ongoing research project at a time. The additional funds will assure full operation of the facility and implementation of security measures consistent with Federal, State, and local requirements. Supplemental funds will allow the work on the BSL–3 pilot plant to be completed as quickly as possible.

II. Funding

It is anticipated that $1.1 million will be made available to fund this urgent, single-source, program expansion supplement in FY 2004.

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26269 Filed 10–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labels, Packaging, Restaurants, and Weight Management; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Department of Health and Human Service's Office of the Assistant Secretary for Planning and Evaluation (OASPE) and FDA's Center for Food Safety and Applied Nutrition (CFSAN), is announcing a public workshop entitled ''Exploring the Connections Between Weight Management and Food Labels and Packaging.'' The workshop is being held in response to the growing concern about obesity in the United States. It is intended to be a science workshop (i.e., nutrition, consumer science, economics, marketing and other relevant sciences) that will look at available data to identify options (and pros and cons) about FDA's food labeling and food packaging requirements that are relevant to consumer weight management decisions.

DATES: The public workshop will be held on November 20, 2003, from 8:30 a.m. to 6 p.m.

Location: The public workshop will be held at the Lister Hill Conference Center, National Institutes of Health Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Amber Jessup, Center for Food Safety and Applied Nutrition (HFS–726), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1689, *amber.jessup@fda.gov*.

Registration: There is no registration fee for the workshop; however, seating is limited. Therefore, interested parties are encouraged to register early. You may register online by clicking on *https://secure.z-techcorp.com/cmt/* (FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). All those planning to preregister must register no later than Friday, November 7, 2003. Registration will close after the workshop is filled. Onsite registration will be done on a space-available basis on the day of the public workshop beginning at 8 a.m. If you have any questions, please contact Karen Ellis at 301–315–2806 or via e-mail at *kellis@z-techcorp.com*. If you need special accommodations due to a disability, please contact Ms. Ellis at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the growing concern about obesity in the United States. The workshop is co-sponsored by FDA, CFSAN and OASPE. The workshop will be of primary interest to nutritionists, marketing experts, social marketing experts, industry, the legal community involved in food labeling and marketing issues, government agencies, consumer groups, and clinicians with obesity expertise. The goal of this science workshop is to