

Dated: May 1, 2000.  
**Bob Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 00-11250 Filed 5-4-00; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Low Income Home Energy Assistance Program (LIHEAP) Leveraging Report.  
*OMB No.:* 0970-0121.

*Description:* The LIHEAP leveraging incentive program rewards LIHEAP grantees that have leveraged nonfederal home energy resources for low income households. The LIHEAP leveraging report is the application for leveraging incentive funds that these LIHEAP grantees submit to HHS for each fiscal year in which they leverage countable resources. Participation in the leveraging incentive program is voluntary. The Leveraging report obtains information on the resources leveraged by LIHEAP grantees each fiscal year (as cash, discounts, waivers, and in-kind); the benefits provided to low income households by these resources (for example, as fuel and payments for fuel, as home heating and

cooling equipment, and is weatherization materials and installation); and the fair market value of these resource/benefits. HHS needs this information in order to carry out statutory requirements for administering the LIHEAP leveraging incentive program, to determine countability and valuation of grantees' leveraged nonfederal home energy resources, and to determine grantees' shares of leveraging incentive funds. HHS proposes to request a 3-year extension of OMB approval for the currently approved LIHEAP leveraging report information collection.

*Respondents:* State and Tribal Governments.

*Annual Burden Estimates:*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP leveraging Report .....	70	1	38	2,660
Estimated total annual burden hours .....				2,660

*Additional Information:* Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

#### OMB Comment

OMB is required to make a decision concerning the 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, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: May 1, 2000  
**Bob Sargis,**  
*Reports Clearance Officer.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Family Assistance; Statement of Organization, Functions and Delegation of Authority; Correction

**AGENCY:** Office of Family Assistance (OFA)/ACF/DHHS.

**ACTION:** Notice; correction.

**SUMMARY:** This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration of Children and Families (ACF) as follows: Chapter KH, The Office of Family Assistance (OFA) (65 FR 8980), as last amended in the **Federal Register** on February 23, 2000. This notice reflects the correction of an administrative code given in OFA's new structure for the Division of TANF Information Network listed on page 8981, the first column, in the notice issued February 23, 2000.

Delete KH.10 Organization in its entirety and replace with the following:

KH.10 Organization. The Office of Family Assistance is headed by a Director, who reports to the Assistant Secretary for Children and Families. The office is organized as follows: Office of the Director (KHA)  
 Division of Policy and Program Development (KHB)  
 Division of Technical Assistance and Training (KHC)

Division of TANF Information Network (KHG)

#### FOR FURTHER INFORMATION CONTACT:

Contact Glenda D. Harden at 202-401-5623.

Dated: May 1, 2000.  
**Alvin C. Collins,**  
*Director, Office of Family Assistance.*  
 [FR Doc. 00-11257 Filed 5-4-00; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1262]

#### Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting public comment on ways to improve the process of premarket review and approval of food and color additive petitions by FDA's Center for Food Safety and Applied Nutrition (CFSAN). CFSAN received substantial new resources for fiscal year 2000 targeted to the premarket review of petitions for approval of new uses of food and color additives. This document is being

published to give all interested parties an opportunity to comment on how these new resources may best be applied to address public health issues related to the timely approval and safe use of food and color additives. CFSAN will consider administrative and procedural enhancements to ensure that program goals are met while maintaining high standards of safety and scientific credibility.

**DATES:** Submit written comments by July 19, 2000.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Alan M. Rulis, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3100, e-mail: arulis@cfsan.fda.gov.

**SUPPLEMENTARY INFORMATION:** The Office of Premarket Approval (OPA) in CFSAN manages the following programs: Petitions for new uses of food and color additives, consultations on foods developed using new methods of biotechnology, generally recognized as safe (GRAS) notices, threshold of regulation (TOR) exemption requests, and premarket notifications for food contact substances (PMN). In addition to these programs, OPA is the lead technical authority for food additives for the U.S. Government. OPA provides expertise and leadership in the international forums of the Joint Food Agricultural Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives, the North American Free Trade Agreement, and the Codex Alimentarius Commission to define international standards, promote harmonization, and evaluate equivalency agreements for food additives and other food ingredients. OPA also has laboratory research and sample analysis components that provide technical support for the enforcement of the food additive regulations.

The current process of reviewing food and color additive petitions has evolved over 40 years since the passage of the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the act). Approvals of food and color additives have been based on a critical scientific evaluation of safety information submitted by petitioners. The primary components of this evaluation are the review of chemical, toxicological, and environmental scientific data and information and an estimation of the probable human

dietary exposure to additives. During its review of safety of new food additive uses, OPA develops an administrative record that relies on scientific data and information to support the agency's safety conclusions. Although this framework has a high level of scientific credibility, CFSAN recognizes that improvements could be made to ensure that the process is more efficient while maintaining the current high scientific standards. With this notice, CFSAN is soliciting comments on ways to improve the timeliness, transparency, and predictability of its review of food and color additive petitions, and its monitoring of the safety of food and color additives over time.

To help focus comments, FDA requests that comments regarding food and color additive review address the following:

1. The act requires that the agency base its safety decisions for the premarket review of additives on "a fair evaluation of the data" and requires that new uses of food additives be consistent with the agency safety standard of "reasonable certainty of no harm." What specific changes can be made to the current review process to make that process more efficient, i.e., transparent, timely, responsive, and predictable, while preserving these high standards of data review and of safety?

2. On January 5, 1999 (64 FR 517), CFSAN made available a guidance describing a policy to expedite the review of petitions for food additives that are intended to significantly decrease human pathogens or their toxins in/on food. Should the Center consider broadening the criteria for eligibility for such expedited petition review? If so, petitions for what types of uses should be added?

3. How should the increased appropriation to CFSAN that is targeted for the safety review of food and color additives be allocated? For example, to what extent should new resources be allocated to: (1) Performing prefilings consultations with prospective applicants for new uses of food ingredients, (2) adding personnel resources to the review process, (3) enhancing electronic data management systems such as automated workflow management or data warehousing, and (4) acquiring or monitoring new safety information on already approved additives?

4. What specific program enhancements should be given the highest priority?

Interested persons may, on or before July 19, 2000, submit to the Dockets Management Branch (address above) written comments regarding this

document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00-11331 Filed 5-4-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Oxytetracycline in Shrimp; Availability of Data

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of human food safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for the treatment of shrimp with oxytetracycline via medicated feed for bacterial infections. The data, contained in Public Master File (PMF) 5662, were compiled by FDA, Center for Veterinary Medicine (CVM), Office of Research (OR).

**ADDRESSES:** Submit NADA's or supplemental NADA's to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Copies of the analytical methods used to analyze the feed and tissue samples used in this study are available from the Center for Veterinary Medicine, Office of Research, 8401 Muirkirk Rd., Laurel, MD 20708.

**FOR FURTHER INFORMATION CONTACT:** Julia A. Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6976.

**SUPPLEMENTARY INFORMATION:**

Oxytetracycline used for the treatment of bacterial infections in shrimp is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, oxytetracycline is subject to section 512 of the act (21 U.S.C. 360b), requiring that its use in shrimp be the subject of an approved NADA or supplemental NADA. Shrimp are a minor species under 21 CFR 514.1(d)(1)(ii).