Office contributes to the development of national policy based on regional perspectives for all ACF programs. It oversees ACF operations and the management of ACF regional staff; coordinates activities across regional programs; and assures that goals and objectives are carried out. The Office alerts the Assistant Secretary for Children and Families to problems and issues that may have significant regional or national impact. It represents ACF at the regional level in executive communications within ACF, with the HHS Regional Director, other HHS operating divisions, other federal agencies, and public or private local organizations representing children and families.

Within the Office of the Regional Hub Director, an administrative staff assists the Regional Hub Director. The staff directs the development of regional work plans related to the overall ACF strategic plan; tracks, monitors and reports on regional progress in the attainment of ACF national goals and objectives; and manages special and sensitive projects. It serves as the focal point for public affairs and contacts with the media, public awareness activities, information dissemination and education campaigns in accordance with the ACF Office of Public Affairs and in conjunction with the HHS Regional Director; and assists the Regional Hub Director in the management of cross-cutting initiatives and activities among the regional components.

The Office provides day-to-day support for regional administrative functions, oversees the management and coordination of automated systems in the region, and provides data management support to all Regional Office components. Administrative functions include budget planning and execution, facility management, employee relations, and human resources development. Data management responsibilities include the development of automated systems application to support and enhance program, fiscal, and administrative operation, and the compilation and analysis of data on demographic and service trends that assist in monitoring and oversight responsibilities.

The Office is responsible for the effective and efficient management of internal ACF automation process. Staff performs an independent grants management function to support the grants processing in the office.

B. The Office of Self-Sufficiency Programs is headed by an Assistant Regional Administrator who reports to the Regional Hub Director and consists of Child Support Enforcement Branch; Child Welfare Branch; and Family Independence/Child Care Branch.

The Office is responsible for providing centralized program, financial management and technical administration of certain ACF formula, entitlement, discretionary and block grant programs, such as Temporary Assistance for Needy Families, Child Support Enforcement, Child Care and Development Fund, Child Welfare Services, Family Preservation and Support, Foster Care and Adoption Assistance, and Child Abuse and Neglect and for oversight of state systems projects for ACF programs. In coordination with other Regional Office components, it monitors state systems projects and is the focal point for technical assistance to states and grantees on the development and enhancement of automated systems.

In that regard the Office provides policy guidance to states to assure consistent and uniform adherence to federal requirements governing formula and entitlement programs. The Office reviews cost estimates and reports from ACF entitlement and formula grant programs, and recommends funding levels.

A Financial/Grants Management Officer is located in each Branch of the Office of Self-Sufficiency Programs to provide expertise in business and other non-programmatic areas of grants administration and to help ensure that grantees fulfill requirements of law, regulations and administrative policies.

The Office establishes regional financial management priorities; reviews cost allocation plans, and makes recommendations to the Regional Hub Director to approve, defer or disallow claims for federal financial participation in ACF formula and entitlement programs. As applicable, it makes recommendations on the clearance and closure of audits of state and grantee programs, paying particular attention to deficiencies that decrease the efficiency and effectiveness of ACF programs and taking steps to resolve such deficiencies.

The Office represents the Regional Hub Director in dealing with ACF central office, states and grantees on all program and financial management policy matters for programs under its jurisdiction. It alerts the Regional Hub Director to problems or issues that have significant implications for the programs.

C. The Office of Community Programs is headed by an Assistant Regional Administrator who reports to the Regional Hub Director and consists of three Head Start and Youth Branches.

The Office is responsible for providing centralized program, financial management and technical administration of certain ACF discretionary programs, such as Head Start and Runaway and Homeless Youth, as well as the Developmental Disabilities program.

A Financial/Grants Management Officer is located in each Branch of the Office of Community Programs to provide expertise in business and other non-programmatic areas of grants administration and to help ensure that grantees fulfill requirements of law, regulations and administrative policies.

The Office establishes regional financial management priorities; reviews cost allocation plans, and makes recommendations to the Regional Hub Director to approve or disallow costs under ACF discretionary grant programs. The Office issues certain discretionary grant awards based on a review of project objectives, budget projections and proposed funding levels. As applicable, it makes recommendations on the clearance and closure of audits of state and grantee programs, paying particular attention to deficiencies that decrease the efficiency and effectiveness of ACF programs and taking steps to resolve such deficiencies.

The Office represents the Regional Hub Director in dealing with ACF central office, states and grantees on all program and financial management policy matters for programs under its jurisdiction. It alerts the Regional Hub Director to problems or issues that have significant implications for the programs.

Dated: September 12, 1997.

Olivia A. Golden,

Principal Deputy Assistant Secretary for Children and Families.

[FR Doc. 97–24989 Filed 9–18–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0182]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collections of information listed below have been

submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 20, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collections of information to OMB for review and clearance.

1. Requests for Samples and Protocols: Official Release—(OMB Control Number 0910–0206—Reinstatement)

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to assure the safety, purity, and potency of biological products and to ensure that licenses for such products are only issued when a product meets the prescribed standards.

Since January 8, 1948, there has been a regulation, now codified under § 610.2 (21 CFR 610.2), that gives authority to FDA to require manufacturers of licensed biological products to submit lot samples and protocols prior to marketing the lot of product. These lot samples and protocols are required by FDA when necessary for the safety, purity, or potency of the product. This requirement remains essential because of the potential lot-to-lot variability of many biological products. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot stability, official lot release is normally not required. In addition to § 610.2, there are other regulations that require additional standards for the submission of samples and protocols for specific licensed biological products: §§ 640.101(f) (21 CFR 640.101(f)) (Immune Globulin (Human)), 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Respondents to this collection of information are manufacturers of licensed biological products that are subject to lot release. Approximately 80 manufacturers are subject to lot release. Previously, 90 firms were subject to lot release, however, 10 of those firms have been exempted from this reporting requirement because the firms manufacture specified biotechnology and/or specified synthetic biological products. FDA estimates are based on data on lot releases submitted in fiscal year 1995. The estimated burdens for §§ 640.101(f), 660.6, 660.36, and 660.46 are included in the estimated annual reporting burden for § 610.2.

In the **Federal Register** of May 30, 1997 (62 FR 29353), the agency requested comments on the proposed collection of information for ''Requests for Samples and Protocols: Official Release.'' The agency received one comment, which suggested a higher estimated average for the time to prepare a protocol for submission to FDA than the agency had estimated. Subsequently, FDA contacted another representative from industry in August 1997 regarding the lot release requirements for § 610.2. The average time estimated herein was adjusted accordingly to reflect the comment received and all four contacts with industry. The burden estimate ranged from 1 to 5.6 hours and the average was rounded to 3 hours.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	80	75	6,500	1	6,500

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

2. Transmittal of Labels and Circulars, Form FDA 2567—21 CFR 601.2(a) and 601.12(a) (OMB Control Number 0910–0039—Reinstatement)

Under section 351 of the PHS Act, FDA reviews the labeling for biological products prior to marketing of the licensed product and when changes to labeling are proposed. Section 601.2(a) (21 CFR 601.2(a)) requires manufacturers of biological products to submit an establishment and product, or biologics license application for review and approval to the Center for Biologics Evaluation and Research (CBER) prior to marketing a biological product in interstate commerce. Specimens of the label are required to be submitted as part of the approval process. Section 601.12(a) (21 CFR 601.12(a)) requires proposed changes to labeling to be submitted to CBER for approval. For these labeling requirements, Form FDA 2567 is used to determine the type of labeling being submitted (container label, package label, diluent label and/or circular) and the type of change(s) to the labeling. This form is also used for the submission of advertising and promotion labeling. The form is composed of two parts: Part I is for the submission of draft and preliminary proof labeling and is completed by manufacturers of biological products, and Part II of the form is submitted upon implementation of final printed labeling. Parts I and II of the form are submitted separately. Respondents to this collection of information are manufacturers of biological products.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA Form 2657 Transmittal of Labels and Circulars	601.2(a) and 601.12(a)	387	7.2	2,800	.16	448

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

Dated: September 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24954 Filed 9–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0378]

Food Code; 1997 Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 1997 revision of the Food Code. This 1997 revision was initiated in cooperation with the Conference for Food Protection (CFP) to help ensure that safe, unadulterated, and honestly presented food is sold or offered for human consumption by retail food establishments.

ADDRESSES: The 1997 revision of the Food Code is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding questions about this document: Betty Harden, Office of Field Programs, Center for Food Safety and Applied Nutrition (HFS–627), 200 C St. SW., Washington, DC 20204, 202–205–8140.

Regarding additional information about the CFP: Leon Townsend, Conference for Food Protection, 110 Tecumseh Trail, Frankfort, KY 40601, 502–695–0253.

SUPPLEMENTARY INFORMATION: FDA provides assistance to local, State, and Federal governmental bodies to ensure that the food that is provided to consumers by retail food establishments is not a vector of communicable diseases. One mechanism for providing that assistance is the publication of a model code that sets out FDA's best advice for a uniform system of regulation to ensure that the food sold or offered for human consumption at retail is safe, properly protected, and accurately presented.

The CFP was originally established in 1971 by State and Federal officials and by representatives of industry. In 1988, the CFP adopted a constitution and by-laws to provide a formal structure under which State regulatory authorities could meet and consider guidelines for improving food safety in the retail segment of the food industry.

At the 1986 CFP meeting, FDA presented a White Paper that recommended combining the three distinct model codes that existed at that time (retail food stores, food service facilities, and vending) into a Food Protection Unicode. The CFP endorsed the approach that FDA would develop a model Food Protection Unicode as a priority project. FDA formed a Unicode Task Group and published a notice of the Unicode's availability for comment in the **Federal Register** of May 9, 1988 (53 FR 16472), when the Task Group completed a draft. Based on comments submitted in response to that notice, and in consideration of subsequent comments provided by regulatory officials, industry representatives, academia, and consumer representatives at the CFP meetings in 1988, 1990, and 1992, FDA modified the document and finalized it as the 1993 Food Code. Based on field application trials, further comment, and input from the 1994 CFP meeting, FDA issued a revised version of the 1993 Food Code as the 1995 Food Code.

The CFP wrote a letter to FDA on May 28, 1996, and suggested changes in the 1995 Food Code. The CFP developed these suggestions in cooperation with the Association of Food and Drug Officials (AFDO).

The 1997 Food Code responds to those suggestions. Noteworthy changes from the 1995 Food Code include the following:

(1) Modification of the definition of potentially hazardous food to specifically state that a food might contain pathogens even though it does not qualify as a potentially hazardous food;

(2) Identification of three methods of complying with the knowledge requirements for the person in charge;

(3) Addition of *Shigella* spp. and *E. coli* O157:H7 to the list of organisms that warrant restriction or exclusion if a food worker is found to be an asymptomatic shedder;

(4) Removal of the special handwashing procedures and reservation of that section;

(5) Allowance for the storage of potentially hazardous food at 45 °F (7 °C) under certain conditions;

(6) Adjustment of the number of days that prepared foods may be stored at 41 °F (5 °C) and 45 °F from 10 to 7 and from 3 to 4, respectively;

(7) Revision of certain cooking temperatures and times, e.g., for preparing ratites and formed roast beef and for microwave cooking;

(8) Modifications throughout the document to coincide with the seafood hazard analysis critical control point rule at 21 CFR parts 123 and 1240;

(9) Provision for the regulatory authority to approve alternatives to the rule of no bare hand contact with ready-to-eat food;

(10) Insertion of an explanation of the current status of the consumer advisory language recommended by the CFP;

(11) Use of the term ''raw shell eggs'' to distinguish provisions that apply to in-shell eggs versus in-shell eggs that were subjected to in-shell pasteurization at a food processing plant;

(12) Addition of a statement that shell eggs placed, upon receipt, in a refrigerated unit that maintains food at the required temperature constitutes satisfactory compliance;

(13) Addition of a section that collates and expands the Food Code's special precautions for highly susceptible populations;

(14) Removal of the requirement for a specified carbonator backflow prevention device and reservation of the section; and

(15) Update of information and addition of user aides in the annexes.

The 1997 revision of the Food Code is available for public examination in