The total burden is 8,520. Send comments to Desk Officer, CDC; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Dated: May 22, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evalution, Center for Disease Control and Prevention (CDC).

[FR Doc. 96–13393 Filed 5–28–96; 8:45 am]

BILLING CODE 4163–18–P

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Plan for the Child Care and Development Block Grant.

OMB No.: 0970–0114.

Description: This legislatively-mandated plan serves as the agreement between the grantee and the Federal Government as to how CCDBG programs will be operated. The plans provide assurances that the funds will be administered in conformance with the legislative requirements, pertinent Federal Regulations, and other applicable instructions or guidelines issued by ACF.

Respondents: State governments.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–700	282	1	40	11,280

Estimated Total Annual Burden Hours: 11,280.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 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, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: May 6, 1996.

Roberta Katson,

Director, Office of Information Resource Management Services.

[FR Doc. 96–13317 Filed 5–28–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 94N–0155]

Nutrient Values for the Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of updated nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States. The agency is making these values available to assist those food retailers who wish to update the voluntary nutrition labeling information that they make available to consumers before FDA's next survey of retail stores to determine whether there is substantial compliance with the voluntary nutrition labeling program.

ADDRESSES: Submit written requests for single copies of the nutrition labeling values to the Division of Technical Evaluation (HFS–165), Office of Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Requests should be identified with the docket number found in brackets in the heading of this document. Send a self-addressed adhesive label or fax number to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Mary M. Bender, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5592, FAX 202–205–5532.

SUPPLEMENTARY INFORMATION: The Nutrition Labeling and Education Act of 1990 amended the Federal Food, Drug, and Cosmetic Act (the act) to require, among other things, that under section 403(q)(4) of the act (21 U.S.C. 343(q)(4)), FDA: (1) Identify the 20 most frequently consumed raw fruits, vegetables, and fish in the United States; (2) establish guidelines for the voluntary nutrition labeling of these raw fruits, vegetables, and fish; and (3) issue regulations that define ''substantial compliance'' with respect to the adherence by food retailers with those guidelines. In the Federal Register of July 2, 1991 (56 FR 30468 at 30479 through 30481), FDA responded to these requirements by issuing a proposal, and, in the Federal Register of November 27, 1991 (56 FR 60880), the agency published a final rule on the nutrition labeling of raw fruits, vegetables, and fish (corrected on March 6, 1992 (57 FR 8174)). In the Federal Register of July 18, 1994 (59 FR 36379) (corrected on July 21, 1994 (59 FR 37190)), FDA published a proposal to revise the guidelines and the labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish. FDA plans to publish a final rule on that rulemaking in the near future.

Under the guidelines of the voluntary labeling program, nutrition labeling information should be provided in close proximity to the place in the retail establishment where raw fruits, vegetables, and fish are displayed for sale. Information may be made available in signs, posters, brochures, notebooks, or leaflets and may be supplemented by video, live demonstration, or other media. Nutrition labeling information may also be provided on the individual food package.

In § 101.43 (21 CFR 101.43), FDA defined substantial compliance to mean that at least 60 percent of the food retailers sampled in a representative survey provide nutrition labeling information (as specified in the guidelines) for at least 90 percent of the foods that they sell that are included on the listing of the most frequently consumed raw fruits, vegetables, and fish. Section 403(q)(4)(C)(ii) of the act states that if substantial compliance is achieved by food retailers, FDA is to reassess voluntary labeling compliance every 2 years. The act also states that, if substantial compliance is not achieved, FDA is to propose to require that nutrition information be provided by any person who offers raw fruits and vegetables or raw fish to consumers (section 403(q)(4)(D)(i)).

Because substantial compliance was achieved in 1993 and 1995, section 403(q)(4)(C)(ii) of the act requires that FDA reassess voluntary labeling compliance and issue a report in 1997. FDA will survey retail stores under contract in November and December of 1996 to determine whether substantial compliance in the voluntary provision of labeling information for raw fruits, vegetables, and fish continues to exist. If substantial compliance is not met, the agency will propose to modify § 101.43 to make the program mandatory.

The industry has informed the agency that many retailers need new posters, charts, or brochures, and rather than reprinting the old values, they would prefer to wait until they have the new values to print the necessary materials. The timeframe by which the agency intends to publish a final rule to update the voluntary labeling program, however, may not allow food retailers and trade associations adequate time to print, distribute, and post nutrition labeling information before the next compliance survey. Therefore, because FDA considers that both industry and consumers will benefit if the most current nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish are made available for use in the voluntary program, FDA is publishing these values at this time, in advance of completion of work on the final rule. The agency encourages retailers to use these new values when they print their posters, charts, or brochures on raw fruits, vegetables, and fish. However, because of the short amount of time before the 1996 survey, FDA is allowing retailers who choose to participate in the voluntary nutrition labeling program to use the old 1991 values or these new values.

Therefore, firms interested in obtaining the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish should submit a written request, accompanied by a self-addressed adhesive label or a fax number, to the Division of Technical Evaluation (HFS–165), Office of Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Dated: May 20, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13309 Filed 5–28–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0045]

Determination of Regulatory Review Period for Purposes of Patent Extension; COREG®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COREG® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product COREG® (carvedilol). COREG® is indicated for the management of essential hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for COREG® (U.S. Patent No. 4,503,067) from Boehringer Mannheim GmbH, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 22, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of COREG® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for COREG® is 3,625 days. Of this time, 2,727 days occurred during the testing phase of the regulatory review period, while 898 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: October 13, 1985. FDA has verified the applicant claim that the day the investigational new drug application became effective was on October 13, 1985.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 31, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for COREG® (NDA 20–297) was initially submitted on March 31, 1993.

3. *The date the application was approved*: September 14, 1995. FDA has verified the applicant's claim the NDA 20–297 was approved on September 14, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.