

from these twenty-three jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodate or explain rule.

When SPOC comments are submitted directly to ACF, they should be addressed to: William Wilson, ACYF's Office of Grants Management, Room 2220 Switzer Building, 330 C Street SW., Washington, DC 20447, Attn: Head Start Discretionary Research Grants Announcement. A list of the Single Points of Contact for each State and Territory can be found on the Web site <http://www.whitehouse.gov/omb/grants/spoc.html>

Dated: February 26, 2002.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 02-5088 Filed 3-1-02; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01D-0294 and 01D-0295]

Agency Information Collection Activities; Announcement of OMB Approval; Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 30, 2001 (66 FR 59796), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0480. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 22, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-4963 Filed 3-1-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0335]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling: Nutrition Labeling of Dietary Supplements on a "Per Day" Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 9, 2001 (66 FR 56687), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0395.

The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 22, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-4964 Filed 3-1-02; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E-0053]

Determination of Regulatory Review Period for Purposes of Patent Extension; Diphenylmethane Diisocyanate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for diphenylmethane diisocyanate 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 food additive.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD-007), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive 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 food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA recently approved for marketing the food additive diphenylmethane diisocyanate. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for diphenylmethane diisocyanate (U.S. Patent No. 4,968,514) from BF Goodrich Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 2, 2001, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of diphenylmethane diisocyanate 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 diphenylmethane diisocyanate is 1,326 days. Of this time, 739 days occurred during the testing phase of the regulatory review period, 587 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test ("test") involving this food additive additive product was begun:* September 23, 1996. FDA has verified the applicant's claim that the test was begun on September 23, 1996.

2. *The date the petition requesting the issuance of a regulation for use of the additive ("petition") was initially submitted with respect to the food additive additive product under section 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348):* October 1, 1998. The applicant claims September 9, 1998, as the date the petition for diphenylmethane diisocyanate was initially submitted. However, FDA records indicate that the petition was submitted on October 1, 1998.

3. *The date the petition became effective:* May 9, 2000. FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on May 9, 2000.

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 962 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by May 3, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 3, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 23, 2002.

Jane A. Axelrad,
Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02-4965 Filed 3-1-02; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of March 2002.

Name: National Advisory Council on the National Health Service Corps.

Date and Time: March 7, 2002, 5:00 p.m.-7 p.m.; March 8, 2002; 8 a.m.-5 p.m.; March 9, 2002; 9 a.m. to 5 p.m.; March 10, 2002; 8 a.m.-10:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Phone: (301) 468-1100.

The meeting is open to the public.

Agenda: The agenda will focus on meeting with the management team from the Agency and the Bureau of Health Professions regarding the Administration's vision and goals for the National Health Service Corps and the designation of health professional shortage areas.

For further information, call Ms. Eve Morrow, Division of National Health Service Corps, at (301) 594-4144.

Agenda items and times are subject to change as priorities dictate.

Dated: February 27, 2002.

Jane M. Harrison,
Director, Division of Policy Review and Coordination.

[FR Doc. 02-5152 Filed 2-28-02; 10:36 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.