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.