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.

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.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel.
Date: February 21, 2002.
Time: 8:30 a.m. to 9:30 a.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Georgetown, 2101 Wisconsin Ave., Washington, DC 20007.

Contact Person: Joel Sherrill, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9606, Bethesda, MD 20892–9606, 301–443–6102, jsherrill@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health Special Emphasis Panel.
Date: March 1, 2002.
Time: 1 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Contact Person: Martha Ann Carey, PhD, RN, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9608, Bethesda, MD 20892–9608, 301–443–1606, mcarey@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health Special Emphasis Panel.
Date: March 11, 2002.
Time: 1 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Contact Person: Richard C. Harrison, Chief, Contract Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Boulevard, Room 3138, MSC 9547, Bethesda, MD 20892–9547, 301–435–1437.