a. The likelihood that program plans and protocols will be finalized within the first year;

b. Proposed site selection, the approximate number of sites to receive WISEWOMAN services, the characteristics of the sites, the proportion of State/Territorial/Tribal BCCEDP sites that will receive WISEWOMAN services, and estimated number of women who are expected to receive such services in the first, second, and subsequent years;

c. Letters of support for WISEWOMAN from the State/Territorial/Tribal BCCEDP site directors and medical staff;

d. A staffing plan;

e. A proposed tracking system for women for referral and follow up and the number and types of interventions provided; and

5. Screening and Interventions (15 Points)

Proposed public health screening and intervention services to be provided along with a time line for determining and implementing screening and intervention services. The adequacy and quality of the proposed rationale and guidelines for implementing eachWISEWOMAN screening and intervention activity; the methods for reaching women from the State/Territorial/Tribal BCCEDP for the purpose of WISEWOMAN screening and intervention; the extent and use of outreach workers to address barriers to program involvement, behavioral change, and maintaining contact for future health screenings and interventions.

6. Evaluation Plan (25 Points)

The extent to which the preliminary evaluation plan provides an appropriate design to examine the impact of chronic disease risk factor intervention(s) on lowering blood pressure and improving cholesterol profiles; collaboration with partners including university partners; evaluation; and data analysis.

7. Budget and Justification (Not Scored)

The extent to which the proposed budget is adequately justified, reasonable, and consistent with this program announcement.

8. Human Subjects (Not Weighted)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements:

Provide CDC with original plus two copies of—

1. Progress reports on a quarterly basis;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in Section J., ''Where to Obtain Additional Information''. The following additional requirements are applicable to this program. For a complete description of each, see Attachment II in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized by sections 1501–1509 (42 U.S.C. 300k–300n–4a) of the Public Health Service Act, as amended. This program is also authorized by the Consolidated Appropriations Act, 2000, Pub. L. 106–113. The Catalogue of Federal Domestic Assistance (CFDA) number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page on the Internet: http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

Should you have questions after reviewing the contents of all the documents, business management assistance may be obtained from: Glynnis Taylor, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Announcement 01098, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2752, E-mail address: gld1@cdc.gov.

For program technical assistance, contact: Julie C. Will, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy, NE., Atlanta, Georgia 30341–4146, Telephone: (770) 488 6024, E-mail address: jxw6@cdc.gov.

Dated: July 2, 2001.

John L. Williams,

Director, Procurement and Grants Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–17039 Filed 7–9–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1254]

Determination of Regulatory Review Period for Purposes of Patent Extension; Gabitril

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Gabitril 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 that claims that human drug product.

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 Grillo, Regulatory Policy Staff (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 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 Gabitril (tiagabine hydrochloride). Gabitril is indicated as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Gabitril (U.S. Patent No. 5,010,090) from Novo Nordisk A/S, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Gabitril represented the first permitted commercial marketing or use of the product. Subsequently, 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 Gabitril is 2,346 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 695 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 (the act) (21 U.S.C. 355(i)) became effective*: May 1, 1991. The applicant claims May 8, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 1, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: November 6, 1995. The applicant claims November 3, 1995, as the date the new drug application (NDA) for Gabitril (NDA 20–646) was initially submitted. However, FDA records indicate that NDA 20–646 was submitted on November 6, 1995.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that NDA 20–646 was approved on September 30, 1997.

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 1,255 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 comments and ask for a redetermination by September 10, 2001. 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 January 7, 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: June 11, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–17103 Filed 7–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0838]

Determination of Regulatory Review Period for Purposes of Patent Extension; Detrol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Detrol 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 that claims that human drug product.

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.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Regulatory Policy Staff (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 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 Detrol (tolterodine tartrate). Detrol is indicated