review group, it will not be considered unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Proposals are judged on the basis of their scientific merit, the theoretical importance of the research question and the appropriateness of the proposed data and methodology to be used in addressing the question.

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Significance and originality of the research.
2. Knowledge of research relevant to the topic.
3. Appropriateness of methods and data, including a description and justification of the analytic techniques that will be employed and a discussion of the methodological problems that might be encountered.
4. Availability and adequacy of data.
5. Organization of the project.
6. Adequacy of facilities and resources. Human subjects involvement and protection (when appropriate).
7. Representation of women and minorities (when appropriate).
8. Appropriateness of the budget.

In evaluating applications and making recommendations reviewers assess the applicant's potential for making significant contributions to the field of minority health statistics research.

Three factors influence the final funding decisions on applications for support of dissertations: (1) Reviewers' evaluation of the application; (2) the potential of the applicant to contribute to the field; and (3) the general needs of the field.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Annual progress reports;
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 David Elswick, Grants Management Specialist, using the address information listed under Section J of this program announcement entitled ''Where to Obtain Additional Information.''

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I. included in the application kit.

AR98–1 Human Subjects Requirements
AR98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR98–4 HIV/AIDS Confidentiality Provisions
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions
AR98–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR98–14 Accounting System Requirements
AR98–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 306(m) of the Public Health Service Act (42 U.S.C. 242k(m)), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

To receive additional written information call 1–888-GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 98100. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

Please refer to announcement number 98100 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained by contacting: David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98100, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., M/S E–13, Atlanta, GA 30305–2209, telephone (404)842–6521.

See also the CDC home page on the Internet: *http://www.cdc.gov*

For program technical assistance, contact: Audrey L. Burwell, M.S., Minority Health Statistics Grants Program Director, National Center for Health Statistics, CDC, 6525 Belcrest Road, Room 1100, Hyattsville, MD 20782, Telephone: (301) 436–7062, extension 127, Email: AZB2@CDC.GOV.

Website: www.cdc.gov/nchswww/about/grants/grants1.htm.

Dated: July 28, 1998.

John L. Williams,

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

[FR Doc. 98–20575 Filed 7–31–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0314]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GEMZAR® 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 GEMZAR® (gemcitabine hydrochloride). GEMZAR® is indicated for use as a firstline treatment for patients with locally advanced (nonresectable stage II or stage III) or metastatic (stage IV) adenocarcinoma of the pancreas in patients previously treated with 5–FU. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GEMZAR® (U.S. Patent No. 4,808,614) from Eli Lilly & 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 March 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GEMZAR® 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 GEMZAR® is 3,293 days. Of this time, 2,824 days occurred during the testing phase of the regulatory review period, 469 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 12, 1987. The applicant claims June 18, 1987, as the date the investigational new drug application (IND) for GEMZAR® became effective. However, FDA records indicate that the IND effective date was May 12, 1987, 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*: February 2, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for GEMZAR® (NDA 20–509) was initially submitted on February 2, 1995.

3. *The date the application was approved:* May 15, 1996. FDA has verified the applicant's claim that NDA 20–509 was approved on May 15, 1996.

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 1,537 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 2, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 1, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–20593 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

District Consumer Forum; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA's), Office of Consumer Affairs (OCA) the Office of Regulatory Affairs (ORA) offices in Illinois, Michigan, and Indiana in cooperation with the U.S. Dept. of Health and Human Services Office of Minority Health, Office of Public Health Sciences, Region V, Illinois Department of Public Health, Center for Minority Health Services and Asian Health Coalition of Illinois, Chicago Department of Health, Chicago Hispanic Health Coalition, U. S. Department of Agriculture Food and Nutrition Service, Regional Office, Midwest Field Office, Health Resources and Services Administration, and the University of Illinois Extension Chicago Cooperative Extension Center is announcing a district consumer forum. The forum will provide an opportunity for consumers, community-based organizations, patient advocates, health professionals, and industry to participate in open discussions on health issues and agency regulatory actions with FDA officials.

Date and Time: The forum will be held on Tuesday, August 18, 1998, from 10 a.m. to 1 p.m.

Location: The forum will be held at the Sears Tower, 233 South Wacker Dr., Lincoln Ballroom, 33d Fl., Chicago, IL 60606.

Contact: Kimberly Phillips, Chicago District Office, Office of Regulatory Affairs, 300 South Riverside Plaza, suite 550–South, Chicago, IL 60606, 312–353–7126, FAX 312–886–3280.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by August 10, 1998. Every effort will be made to accommodate all registrants. However because space is limited, admittance is on a ''first come, first serve basis.''

If you need special accommodations due to a disability, please contact Kimberly Phillips (address above) by August 10, 1998.

Transcripts: Transcripts of the forum may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the forum, at a cost of 10 cents per page.

Dated: July 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20595 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F