H. Budget: The extent to which the budget is reasonable and consistent with the intended use of the program funds. (Not Weighted)

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, no later than 60 days after the application deadline date. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date. Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305. This should be done no later than 60 days after the application deadline date. The granting agency does not guarantee to ''accommodate or explain'' for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305 on or before July 14, 1995.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information package on application procedures, an application package, and business management technical assistance may be obtained from Nealean K. Austin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Atlanta, GA 30305, telephone (404) 842–6512.

Programmatic technical assistance may be obtained from Kathryn Sunnarborg or William Thomas, Technical Information Specialist, Technical Information Services Branch, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), Mailstop K–13, 4770 Buford Highway, NE., Atlanta, GA 30341–3724, telephone (404) 488–5080.

Please refer to Announcement Number 540 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: May 22, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and And Prevention (CDC).

[FR Doc. 95–12954 Filed 5–25–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket Nos. 76N–0048 and 95D–0094]

Compliance Policy Guides (CPG's); Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of six CPG's because they contain outdated regulatory guidance. This action is being taken to ensure that FDA's CPG's reflect current FDA policy.

EFFECTIVE DATE: May 26, 1995.

FOR FURTHER INFORMATION CONTACT: Ronald C. Varsaci, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251.

SUPPLEMENTARY INFORMATION: FDA is revoking the following six CPG's because they contain outdated regulatory guidance:

(1) CPG 7101.02—''Caffeine, Ingredient in Carbonated Beverages''

(2) CPG 7105.06—''Orgeat or 'Orzata' Sirup, Definition and Labeling''

(3) CPG 7105.08—''Sirup-Labeling—Use of Descriptive Statements''

(4) CPG 7105.10—''Candy Pills—Representation as Drugs''

(5) CPG 7128.01—''Bithionol in Cosmetics''

(6) CPG 7108.19—''Polychlorinated Biphenyls (PCB's) in Certain Freshwater Fish''

Dated: May 15, 1995.

Gary J. Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 95–13034 Filed 5–25–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0055]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FRAGMIN® 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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

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 FRAGMIN® (dalteparin sodium). FRAGMIN® is indicated for prophylaxis against deep vein thrombosis, which may lead to pulmonary embolism, in patients undergoing abdominal surgery who are at risk for thromboembolic complications. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FRAGMIN® (U.S. Patent No. 4,303,651) from Pharmacia Aktiebolag, 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 23, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FRAGMIN® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the products's regulatory review period.

FDA has determined that the applicable regulatory review period for FRAGMIN® is 3,555 days. Of this time, 2,832 days occurred during the testing phase of the regulatory review period, while 723 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 (21 U.S.C. 355(i)) became effective*: March 31, 1985. The applicant did not state an investigational new drug application (IND) effective date, stating that foreign studies were used in lieu of an IND. However, FDA records indicate that certain studies material to the approval of the product were conducted under IND 25,924. Therefore, the IND effective date was March 31, 1985, which was 30 days after FDA receipt of IND 25,924.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: December 30, 1992. The applicant claims February 28, 1993, as the date the new drug application (NDA) for FRAGMIN® (NDA 20–287) was initially submitted, whereas it is actually the filing date. FDA records indicate that NDA 20–287 was refused to file on September 25, 1992. The correct resubmission date for NDA 20–287 is December 30, 1992, which was the date the resubmission was actually received by the agency. Therefore, the NDA initial submission date for NDA 20–287 is December 30, 1992, the same as the resubmission date.

3. *The date the application was approved*: December 22, 1994. FDA has verified the applicant's claim that NDA 20–287 was approved on December 22, 1994.

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 661 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may on or before July 25, 1995, 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 November 22, 1995, 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: May 15, 1995

Stuart L. Nightingale,

Associate Commissioner for Health Afairs.

[FR Doc. 95–13032 Filed 5–25–95; 8:45 am]

BILLING CODE 4160–01–F