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 Emadine™ (emedastine difumarate). Emadine™ is indicated for the temporary relief of the signs and symptoms of allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Emadine™ (U.S. Patent No. 4,430,343) from Kanebo, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 10, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Emadine™ 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 Emadine™ is 1,410 days. Of this time, 766 days occurred during the testing phase of the regulatory review period, while 644 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*: February 20, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 20, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: March 26, 1996. The applicant claims March 22, 1996, as the date the new drug application (NDA) for Emadine™ (NDA 20–706) was initially submitted. However, FDA records indicate that NDA 20–706 was submitted on March 26, 1996.

3. *The date the application was approved*: December 29, 1997. FDA has verified the applicant's claim that NDA 20–706 was approved on December 29, 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 1,028 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 29, 1999, 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 July 26, 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: January 18, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–1792 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1268]

Guidance for Industry on Variations in Drug Products That May Be Included in a Single Abbreviated New Drug Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Variations in Drug Products That May Be Included in a Single ANDA.'' This guidance was developed by the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research to provide information to applicants on certain specific variations of a drug product that should be included in a single abbreviated new drug application (ANDA) and describe the general factors to be considered when determining whether single or multiple ANDA's should be submitted. It is intended to reduce the burden on industry for submitting and maintaining separate applications for certain variations of the same drug product.

DATES: Written comments may be submitted on the guidance by April 27, 1999. General comments on agency guidances are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Variations in Drug Products That May Be Included in a Single ANDA'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. West, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5846.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Variation in Drug Products That May Be Included in a Single ANDA.'' Prior

to October 1, 1990, applicants were to submit separate ANDA's for each dosage form of a drug product and also for each variation (e.g., strength, color, shape) within a dosage form. Separate applications were requested for ease of review since having information on a number of variations within one application could make review more difficult. On October 1, 1990, the OGD Interim Policy and Procedure Guide (PPG) 20–90 was issued. This guide permitted certain variations of solid oral dosage forms and injectables to be submitted within a single abbreviated application. On June 7, 1995, PPG 20–90 was amended to allow certain variations to be filed as supplements.

This guidance incorporates the policies and procedures in PPG 20–90 and clarifies the practice of permitting variations of products in a single application.

This guidance is being issued as a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because it is intended to reduce the burden on industry. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance represents the agency's current thinking on variations in drug products that may be included in a single abbreviated application. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments 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. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1850 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1218]

Blood Standards; Pilot Program for Gamma Irradiated Blood and Blood Components and Draft ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to establish a pilot program for licensed blood product manufacturers seeking to market irradiated blood components in interstate commerce. FDA is also announcing the availability for public comment of a draft guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing.'' FDA is proposing a pilot program that would allow a manufacturer to self-certify conformance to specific criteria as a substitute for the Center for Biologics Evaluation and Research (CBER) review of information submitted in a biologics license application (BLA) supplement filing. Instead of submitting a BLA supplement with supporting operating procedures and data derived from validation and quality control testing, the manufacturer would submit an application form (FDA Form 356h), a self-certification statement that provides that the manufacturer is in compliance with all applicable FDA regulations and meets the criteria for gamma irradiated blood and blood components set forth in the draft guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing,'' as well as written request to the CBER Director for an exception to filing a detailed supplement. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments on the proposed pilot program and draft guidance document may be submitted at any time, however, comments should be submitted by April 27, 1999, to ensure their adequate consideration in preparation of the final document and for the initiation of the pilot program.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments and letters of interest on the proposed pilot program and the draft guidance document to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intent to launch a pilot program for licensed blood product manufacturers seeking to market irradiated blood components in interstate commerce. The pilot program provides that FDA will review for completeness FDA Form 356h, the self-certification, and written request for an exception to filing a detailed supplement and at FDA discretion will schedule a prelicense inspection within 90 days of receipt of the self-certification to confirm conformance with applicable Federal regulations and the recommended criteria contained in the draft guidance document.

To participate in the program a manufacturer must already be licensed for nonirradiated blood components and should be ready for a prelicense inspection at the time it forwards FDA Form 356h, self-certification, and request for exception to FDA. If, during the prelicense inspection, FDA finds significant deficiencies in quality assurance, manufacturing facilities, or product safety, purity, potency, or effectiveness, FDA may withdraw the manufacturer from the pilot program and the manufacturer will be required to submit a BLA supplement with complete supporting documentation