biological product and CGMP regulations for blood and blood components in 21 CFR parts 600 through 680, and the CGMP regulations in 21 CFR parts 210 through 211. In addition, the guideline contains a glossary, a reference page, and an appendix that provides examples of the regulations in 21 CFR parts 210, 211, and 21 CFR parts 600 through 680 supplementing each other.

This document is not being issued under the authority of 21 CFR 10.90(b) because FDA is in the process of revising this section. This document, although called a guideline, does not bind the agency and does not create or confer any rights, privileges, or benefits for or on any person. Blood establishments may follow the guideline or may choose to use alternative procedures not provided in the guideline. If a blood establishment chooses to use alternative procedures, the establishment may wish to discuss the matter further with the agency to prevent expenditure of resources on activities that may be unacceptable to FDA.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guideline. 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. Continued comment by the blood industry is encouraged, and comments will be continuously accepted by the Dockets Management Branch.

FDA periodically will review written comments on the guideline to determine whether future revisions to the guideline are warranted.

Dated: July 11, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–17346 Filed 7–13–95; 8:45 am]

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[Docket No. 93E–0076]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RENORMAX® 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 RENORMAX® (spirapril hydrochloride). RENORMAX® is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for RENORMAX® (U.S. Patent No. 4,470,972) from Schering Corp., 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 12, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of RENORMAX® represented the first permitted commercial marketing or use of the procduct. 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 RENORMAX® is 3,996 days. Of this time, 2,901 days occurred during the testing phase of the regulatory review period, while 1,095 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*: January 22, 1984. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on January 22, 1984.

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 31, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for RENORMAX® (NDA 20–240) was initially submitted on December 31, 1991.

3. *The date the application was approved*: December 29, 1994. FDA has verified the applicant's claim that NDA 20–240 was approved on December 29, 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 730 days of patent term restoration.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 12, 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 January 15, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition