broadcast advertising. (This information has colloquially been referred to as the ''major statement.'')

If FDA required or permitted more limited risk information in place of the current brief summary, what specific information should be included? What criteria should be used by manufacturers and the agency to identify the ''major'' risk information for any particular product? FDA is also interested in empirical research that specifically addresses the issues of how much and what kind of risk information can and should be communicated in DTC advertising of prescription drug and biological products.

2. Some comments suggested that risk information could be communicated to consumers through standardized general disclosures. This kind of disclosure would not reference particular characteristics of a product. Instead, such statements would reference one or more general risks, such as the fact that all prescription drug and biological products have side effects; that they are only available from a physician or other prescribing health care professional; that they have significant benefits, but may have significant risks; that patients should discuss product risks with a physician, etc.

Such disclosures, however, are susceptible to habituation or ''wear-out,'' which results in the viewer quickly learning to ignore the message, thus lowering its effectiveness. In addition, such messages may not be perceived as risk messages at all, but instead interpreted as reassurances. If the latter is the case, these messages would not fulfill the purpose of the brief summary requirement, which helps ensure that advertising conveys a balanced impression about the product's benefits and risks.

FDA solicits comments on the effectiveness of such standardized general disclosures at transmitting risk information. FDA is especially interested in any research that addresses the issue of the effectiveness of general risk disclosures of the type described above.

3. Promotional materials appear in very different media that each have distinctive characteristics (e.g., print, broadcast, telephone communications, facsimile, Internet). Should FDA require or permit different disclosures for consumer-directed promotion of prescription drug and biological products that appears in different media, to reflect the capabilities of these varying media, or should the disclosure be the same regardless of medium? For example, should print media contain longer and more complete information than broadcast media because such information could be made readily available at minimal cost and because consumers of print media may be more willing, able, and/or desirous of obtaining more complete information?

4. Different products have different degrees of effectiveness. In some cases, a product that works for a relatively small percentage of the appropriate patient population is approved either because it is the only available therapy for a condition; because all other therapies for the condition also have only modest benefits; or because it has relatively few risks. Should FDA require the communication of the degree of product effectiveness in DTC promotion? How could this information be communicated most effectively?

5. It has been suggested that toll-free telephone numbers are one way that product sponsors could make required information available to audiences. FDA requests comments and information from consumers, health professionals, product sponsors and other interested individuals regarding: (a) How useful toll-free numbers are as a mechanism for obtaining or disseminating information about medical products, and (b) the costs to a sponsor of using toll-free numbers as a means of disseminating information.

FDA welcomes comments on all of the issues described above and especially invites the submission of relevant empirical research.

Dated: May 8, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–12022 Filed 5–13–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0043]

Determination of Regulatory Review Period for Purposes of Patent Extension; EPIVIR™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EPIVIR™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application of 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, 12420 Parklawn Dr., rm. 1–23, 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 EPIVIR™ (lamivudine). EPIVIR™ in combination with Retrovir® (zidovudine) is indicated for the treatment of human immunodeficiency virus infection when therapy is warranted based on clinical and/or immunological evidence of disease progression. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EPIVIR™ (U.S. Patent No. 5,047,407) from Glaxo Wellcome, Inc., 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 1, 1996, FDA advised the Patent and Trademark Office that this human

drug product had undergone a regulatory review period that the approval of EPIVIR™ 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 EPIVIR™ is 1,582 days. Of this time, 1,448 days occurred during the testing phase of the regulatory review period, while 134 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*: July 21, 1991. The applicant claims July 24, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 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 Federal Food, Drug, and Cosmetic Act*: July 7, 1995. The applicant claims June 29, 1995, as the date the new drug application (NDA's) for EPIVIR™ (NDA's 20–564 and 20–596) were initially submitted. However, FDA records indicate that NDA's 20–564 and 20–596 were submitted on July 7, 1995 (the date the User Fee checks were received by the agency). Both NDA's were originally received by the agency on June 30, 1995, unaccompanied by the appropriate User Fee checks. Review of a NDA does not begin until the correct amount of User Fee money has been received by the agency from the sponsor of the NDA.

3. *The date the application was approved*: November 17, 1995. FDA has verified the applicants's claim that NDA's 20–564 and 20–596 were approved on November 17, 1995.

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 836 days of patent term extension..

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 15, 1996, 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 12, 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 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: April 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–12092 Filed 5–13–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0408]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRUSOPT® 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 TRUSOPT® (dorzolamide hydrochloride). TRUSOPT® is indicated in the treatment for elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TRUSOPT® (U.S. Patent No. 4,797,413) from Merck & Co., Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 26, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TRUSOPT® 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 TRUSOPT® is 2,101 days. Of this time, 1,736 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates: