MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the March 18, 1996, Board meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Review of Arthur Andersen annual financial audit.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs (202) 942–1640.

Dated: April 2, 1996.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 96–8591 Filed 4–3–96; 10:18 am]

BILLING CODE 6760–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0033]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OPTIMMUNE® 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 animal 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product OPTIMMUNE® (cyclosporine). OPTIMMUNE® is indicated for treatment of chronic keratoconjunctivitis sicca in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OPTIMMUNE® (U.S. Patent No. 4,839,342) 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 February 8, 1996, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of OPTIMMUNE® represented the first commercial marketing 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 OPTIMMUNE® is 1,898 days. Of this time, 1,668 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: May 24, 1990. The applicant claims May 10, 1990, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the INAD was May 24, 1990, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: December 16, 1994. The applicant claims December 14, 1994, as the date the new animal drug application (NADA) for OPTIMMUNE® (NADA 141–052) was initially submitted. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the NADA was December 16, 1994, which is considered to be the NADA initially submitted date.

3. *The date the application was approved*: August 2, 1995. FDA has verified the applicant's claim that NADA 141–052 was approved on August 2, 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 698 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 4, 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 October 2, 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: March 28, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–8474 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 95E–0418 and 95E–0419]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FLOLAN® 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 FLOLAN® (epoprostenol sodium). FLOLAN® is indicated for the long-term intravenous treatment of primary pulmonary hypertension in New York Heart Association Class III and Class IV patients. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for FLOLAN® (U.S. Patent Nos. 4,338,325 and 4,883,812) from Glaxo Wellcome Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In letters dated February 8, 1996 (U.S. Patent No. 4,338,325), and February 22, 1996 (U.S. Patent No. 4,883,812), FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FLOLAN® 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 FLOLAN® is 5,927 days. Of this time, 5,357 days occurred during the testing phase of the regulatory review period, while 570 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 1, 1979. The applicant claims June 29, 1979, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 1, 1979, which was 30 days after FDA receipt of IND 16,459 on June 1, 1979

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*: February 28, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for FLOLAN® (NDA 20–444) was initially submitted on February 28, 1995.

3. *The date the application was approved*: September 20, 1995. FDA has verified the applicant's claim that NDA 20–444 was approved on September 20, 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 730 days (U.S. Patent No. 4,338,325) and 1,346 days (U.S. Patent No. 4,883,812) of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 4, 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 October 2, 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: March 28, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–8363 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

Small Business Participation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a small business exchange meeting to create a dialogue between the small business community, particularly businesses owned and operated by minorities and women, and FDA officials. The meeting will be chaired by Arthur J. Beebe, Jr., Regional Food and Drug Director, Northeast Region, and it