Because substantial compliance was achieved in 1993 and 1995, section 403(q)(4)(C)(ii) of the act requires that FDA reassess voluntary labeling compliance and issue a report in 1997. FDA will survey retail stores under contract in November and December of 1996 to determine whether substantial compliance in the voluntary provision of labeling information for raw fruits, vegetables, and fish continues to exist. If substantial compliance is not met, the agency will propose to modify § 101.43 to make the program mandatory.

The industry has informed the agency that many retailers need new posters, charts, or brochures, and rather than reprinting the old values, they would prefer to wait until they have the new values to print the necessary materials. The timeframe by which the agency intends to publish a final rule to update the voluntary labeling program, however, may not allow food retailers and trade associations adequate time to print, distribute, and post nutrition labeling information before the next compliance survey. Therefore, because FDA considers that both industry and consumers will benefit if the most current nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish are made available for use in the voluntary program, FDA is publishing these values at this time, in advance of completion of work on the final rule. The agency encourages retailers to use these new values when they print their posters, charts, or brochures on raw fruits, vegetables, and fish. However, because of the short amount of time before the 1996 survey, FDA is allowing retailers who choose to participate in the voluntary nutrition labeling program to use the old 1991 values or these new values.

Therefore, firms interested in obtaining the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish should submit a written request, accompanied by a self-addressed adhesive label or a fax number, to the Division of Technical Evaluation (HFS–165), Office of Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Dated: May 20, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13309 Filed 5–28–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0045]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COREG® 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, 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 COREG® (carvedilol). COREG® is indicated for the management of essential hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for COREG® (U.S. Patent No. 4,503,067) from Boehringer Mannheim GmbH, 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 22, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of COREG® 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 COREG® is 3,625 days. Of this time, 2,727 days occurred during the testing phase of the regulatory review period, while 898 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*: October 13, 1985. FDA has verified the applicant claim that the day the investigational new drug application became effective was on October 13, 1985.

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*: March 31, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for COREG® (NDA 20–297) was initially submitted on March 31, 1993.

3. *The date the application was approved*: September 14, 1995. FDA has verified the applicant's claim the NDA 20–297 was approved on September 14, 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 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 29, 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 25, 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: May 13, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–13307 Filed 5–28–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0036]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FOSAMAX® 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, 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 FOSAMAX® (alendronate sodium). FOSAMAX® is indicated for the treatment of osteoporosis in postmenopausal women and Paget's disease of bone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FOSAMAX® (U.S. Patent No. 4,621,077) from Instituto Gentili S.p.A., 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 and that the approval of FOSAMAX® 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 FOSAMAX® is 2,558 days. Of this time, 2,375 days occurred during the testing phase of the regulatory review period, while 183 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*: September 29, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on September 29, 1988.

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*: March 31, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for FOSAMAX® (NDA 20–560) was initially submitted on March 31, 1995.

3. *The date the application was approved*: September 29, 1995. FDA has verified the applicant's claim that NDA 20–560 was approved on September 29, 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 1,369 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 29, 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 25, 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.