(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 MERETEK UBT™ Breath Test (urea, C–13). MERETEK UBT™ Breath Test is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the diagnosis of *H. pylori* infection in adult patients. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MERETEK UBT™ Breath Test (U.S. Patent No. 4,830,010) from Meretekdiagnostics, 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 February 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MERETEK UBT™ Breath Test 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 MERETEK UBT™ Breath Test is 2,023 days. Of this time, 1,527 days occurred during the testing phase of the regulatory review period, while 496 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:* March 7, 1991. The applicant claims January 19, 1990, as the date the investigational new drug application (IND) for MERETEK UBT™ Breath Test (IND 26,861) became effective. However, FDA records indicate that IND 26,861 was received by the agency on August 7, 1985. The protocol that first contained the Urea Breath Test was received by the agency on February 5, 1991, as part of this IND. Using February 5, 1991, as the beginning date plus adding 30 days for the receipt date of the modification, results in an effective date of March 7, 1991, for the testing phase of the active ingredient of this product.

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:* May 11, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for MERETEK UBT™ Breath Test (NDA 20–586) was initially submitted on May 11, 1995.

3. *The date the application was approved*: September 17, 1996. FDA has verified the applicant's claim that NDA 20–586 was approved on September 17, 1996.

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 780 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 3, 1997 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 1, 1997 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 27, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–8625 Filed 4–3–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97E–0014]

Determination of Regulatory Review Period for Purposes of Patent Extension; Astelin® Nasal Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Astelin® Nasal Spray 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 Astelin® Nasal Spray (azelastine hydrochloride). Astelin® Nasal Spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis such as rhinorrhea, sneezing, and nasal pruritus in adults and children 12 years and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Astelin® Nasal Spray (U.S. Patent No. 5,164,194) from Astra Medica AG, 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 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Astelin® Nasal Spray 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 Astelin® Nasal Spray is 2,797 days. Of this time, 749 days occurred during the testing phase of the regulatory review period, while 2,048 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*: March 8, 1989. The applicant claims February 6, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 8, 1989, which was 30 days after FDA receipt of the IND on February 6, 1989.

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 26, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for Astelin® Nasal Spray (NDA 20–114) was initially submitted on March 26, 1991.

3. *The date the application was approved*: November 1, 1996. FDA has verified the applicant's claim that NDA 20–114 was approved on November 1, 1996.

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 349 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 3, 1997 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 1, 1997 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 27, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–8626 Filed 4–3–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Pretesting of Office of Cancer Communications Messages; Proposed Collection; Comment Request

Summary: In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Pretesting of Office of Cancer Communications Messages.

Type of Information Collection Request: EXTENSION (OMB # 0925–0046, expires 8/31/97).

Need and Use of Information Collection: In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection diagnosis, and treatment to a wide variety of audiences and organizations (e.g. cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations), the Office of Cancer Communications (OCC) needs to pretest its communications strategies, concepts, and messages while they are under development. The primary purpose of this pretesting, or formative evaluation, is to ensure that the messages, communications materials, and information services created by OCC have the greatest capacity of being received, understood, and accepted by their target audiences. By utilizing appropriate qualitative and quantitative methodologies, OCC is able to (1) Understand characteristics of the intended target audience—their attitudes, beliefs and behaviors—and use this information in the development of effective communications tools; (2) produce or refine messages that have the greatest potential to influence target audience attitudes and behavior in a positive manner; and (3) expend limited program resources dollars wisely and effectively. *Frequency of Response:* On occasion. *Affected public:* Individuals or households; Businesses or other for