human drug product under section 505 of the act: December 22, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for EXTRANAEAL (NDA 21–321) was initially submitted on December 22, 2000.

3. *The date the application was approved:* December 20, 2002. FDA has verified the applicant's claim that NDA 21–321 was approved on December 20, 2002.

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 1,467 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 6, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 4, 2004. 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 Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–2546 Filed 2–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0081]

Determination of Regulatory Review Period for Purposes of Patent Extension; ORTHO-EVRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ORTHO-EVRA 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Director 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 ORTHO-EVRA (norelgestromin/ethinyl estradiol transdermal system). ORTHO-EVRA is indicated for the prevention of pregnancy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ORTHO-EVRA (U.S. Patent No. 5,876,746) from Johnson and Johnson, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ORTHO-EVRA represented the first permitted commercial marketing or use of the product. 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 ORTHO-EVRA is 2,001 days. Of this time, 1,666 days occurred during the testing phase of the regulatory review period, while 335 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 (the act) (21 U.S.C. 355(i)) became effective:* May 31, 1996. The applicant claims May 30, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 31, 1996, 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 of the act:* December 21, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for ORTHO-EVRA (NDA 21–180) was initially submitted on December 21, 2000.

3. *The date the application was approved:* November 20, 2001. FDA has verified the applicant's claim that NDA

21–180 was approved on November 20, 2001.

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 664 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written comments or electronic comments and ask for a redetermination by April 6, 2004. Furthermore, any interested person may petition FDA, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 4, 2004. 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 Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–2547 Filed 2–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Extension of General Program Test Regarding Post Entry Amendment Processing

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that the general program test regarding post entry amendment processing is being extended for a one year period. The test will continue to operate in accordance with the notice published in the **Federal Register** on November 28, 2000, as modified by the notice published in the **Federal Register** on February 20, 2003.

DATES: The test allowing post entry amendment to entry summaries is extended to December 31, 2004.

FOR FURTHER INFORMATION CONTACT: Don Yando, Chief, Entry and Drawback Branch, Office of Field Operations, 202–927–1082 or Debbie Scott, Entry and Drawback Branch, OFO, 202–927–1962.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Customs and Border Protection (CBP) announced and described the post entry amendment processing test in a general notice document published in the **Federal Register** (65 FR 70872) on November 28, 2000. That notice announced that the test would commence no earlier than December 28, 2000, and run for approximately one year. On January 7, 2002, CBP published a general notice in the **Federal Register** (67 FR 768) extending the test for a one year period to December 21, 2002. CBP published another general notice in the **Federal Register** (68 FR 8329) on February 20, 2003, extending the test for an additional year to December 31, 2003.

This document announces that the test is being extended to December 31, 2004. The test allows importers to amend entry summaries (not informal entries) prior to liquidation by filing with CBP either an individual amendment letter upon discovery of an error or a quarterly tracking report covering any errors that occurred during the quarter. The November 28, 2000, general notice described how to file post entry amendments for revenue related errors and non-revenue related errors and the consequences of misconduct by importers during the test. It also provided that there are no application procedures or eligibility requirements. To participate in the test, an importer need only follow the procedure for making a post entry amendment set forth in the November 28, 2000, general notice.

Comments received in response to the previously published general notices have been reviewed and CBP continues to evaluate the test. Changes to the test based on the comments and the evaluation will be announced in the **Federal Register** in due course. The test may be further extended if warranted. Additional information on the post entry amendment procedures can be found under ''import'', then ''cargo summary'' at *http://www.cbp.gov.*

Dated: February 3, 2004.

Jayson P. Ahern,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 04–2589 Filed 2–5–04; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4903–N–06]

Notice of Submission of Proposed Information Collection to OMB: Application for Healthy Homes and Lead Hazard Control Programs Grant Funding

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

This submission is a request for an extension of the approval to collect information for the applications for Healthy Homes and Lead Hazard Control Program Grant Funding to address and reduce the lead-based paint and other hazards in privately owned housing. Some of the information in the applications has be reformatted in a number of forms.

DATES: *Comments Due Date:* March 8, 2004.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and OMB approval number (2539–0015) and should be sent to: Melanie Kadlic, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; fax number (202) 395–6974; e-mail *Melanie_Kadlic@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins or on HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal