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 act:* February 20, 1998. The applicant claims February 17, 1998, as the date the new animal drug application (NADA) for Bapten® (NADA 141–107) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141–107 was February 20, 1998, which is considered to be the initially submitted date for NADA 141–107.

3. *The date the application was approved:* June 10, 1998. FDA has verified the applicant's claim that NADA 141–107 was approved on June 10, 1998.

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 April 3, 2000, 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 July 31, 2000, 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: December 23, 1999.

Jane A. Axelrad,

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

[FR Doc. 00–2149 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–0116]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Rotashield® 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 biological product.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product Rotashield®. Rotashield® is indicated for immunization of infants at 2, 4, and 6 months of age. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Rotashield® (U.S. Patent No. 4,704,275) from American Home Products 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 March 16, 1999, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Rotashield® 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 Rotashield® is 3,804 days. Of this time, 3,226 days occurred during the testing phase of the regulatory review period, while 578 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:* April 3, 1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 3, 1988.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act:* January 31, 1997. FDA has verified the applicant's claim that the product license application (PLA) for Rotashield® (PLA 97–0111) was initially submitted on January 31, 1997.

3. *The date the application was approved:* August 31, 1998. FDA has verified the applicant's claim that PLA 97–0111 was approved on August 31, 1998.

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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 3, 2000, 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 July 31, 2000, 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: December 23, 1999.

Jane A. Axelrad,

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

[FR Doc. 00–2243 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0392]

Seafood HACCP Transition Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Seafood HACCP Transition Guidance.'' This guidance sets forth the policies and procedures under which the agency may consider refraining from regulatory action under the seafood Hazard Analysis Critical Control Point (HACCP) regulations and the Federal Food, Drug, and Cosmetic Act (the act). This guidance provides for the submission to FDA of citizen petitions that describe scientific studies that petitioners are proposing to resolve issues relating to particular hazard analyses or controls for particular food safety hazards.

DATES: This notice is effective February 2, 2000.

FOR FURTHER INFORMATION CONTACT: Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 26, 1999 (64 FR 14736), FDA published for comment a notice containing a draft guidance setting forth policies and procedures under which the agency may take into account a planned or ongoing scientific study when deciding whether to pursue regulatory action under the seafood HACCP regulations and the act. Specifically, the draft guidance indicated that FDA might consider refraining from regulatory action against a seafood processor or processors to allow the conduct of a scientific study to resolve a dispute between FDA and the processor(s) over questions of fact. These questions would either relate to whether certain food safety hazards are reasonably likely to occur in specific situations or to the effectiveness or need for certain controls for those hazards. FDA would only consider refraining from regulatory action if the public would not be jeopardized by doing so.

The draft guidance requested that individuals desiring to propose a scientific study under these circumstances submit a petition to the agency in accordance with FDA's regulations for citizen's petitions at 21 CFR 10.30. The petition would describe the study and request that FDA consider exercising enforcement discretion on certain matters under the seafood HACCP regulations and the act pending their scientific resolution.

FDA further recommended that the petition be submitted as a request to revise or amend the agency's guidance document entitled ''The Fish and Fishery Products Hazards and Controls Guide (the Guide).'' The Guide contains FDA's compilation of what the agency believes to be the latest, science-based knowledge about when food safety hazards are reasonably likely to occur and what controls are appropriate for those hazards.

II. The Comments

Three comments were received on the draft of the Seafood HACCP Transition Guidance. Two of the comments were from trade associations, and one was from a professional association. All comments supported the general approach proposed by the agency to rely on scientific studies under circumstances described in the draft, but asked for specific modifications in order to expedite or otherwise improve the process.

1. One comment suggested that the petition process would be time consuming and would inhibit the agency's ability to respond quickly to requests for discretionary enforcement, especially considering that the agency allows itself up to 180 days to respond on petitions.

As noted by the comment, the 180-day period is the maximum permitted tentative response time. However, given the significance of the food safety issues that are likely to be submitted for review under the guidance and the desire of the agency to obtain new scientific information on issues having bearing on scientific questions related to HACCP implementation, FDA believes that it would be mutually advantageous for the agency to respond to the petitioner as expeditiously as possible. For this reason, the agency continues to encourage potential petitioners to engage in presubmission consultations with FDA on the merits. Familiarity with the issues presented in a petition would greatly facilitate the agency's ability to respond quickly. The agency anticipates that review of the scientific merits of any proposal will be a more likely cause of delay, than the mechanics of the petition process. Consequently, FDA does not agree that the citizen's petition process will cause the agency to significantly delay its response.

A related comment stated that the citizen's petition is a cumbersome mechanism, which could be overwhelming for those unaccustomed to FDA's administrative procedures. This comment recommended that the guidance policy clarify the applicability of certain provisions in part 10 (21 CFR part 10), particularly as they relate to the need for environmental and economic impact statements.

FDA does not anticipate that the contents of a citizen's petition would be notably different than the contents of a request to the agency under another format. The contents need only include information that enables FDA to make an informed decision on a petitioner's request. In that regard, the agency does not expect that either an environmental or economic impact statement will be relevant, especially since the research to be conducted is at the petitioner's initiative and would not ordinarily be