

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E-0257]

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Determination of Regulatory Review Period for Purposes of Patent Extension; Neotame

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for neotame 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 which claims that food additive.

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:

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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 food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive. 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 food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g) (2) (B).

FDA recently approved for marketing the food additive neotame. Neotame is a nonnutritive sweetener in food. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for neotame (U.S. Patent No. 5,480,668) from The NutraSweet Co., 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 food additive had undergone a regulatory review period and that the approval of neotame 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 neotame is 3,143 days. Of this time, 1,503 days occurred during the testing phase of the regulatory review period, 1,640 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a major health or environmental effects test ("test") involving this food additive was begun: December 2, 1993. FDA has verified the applicant's claim that the test was begun on December 2, 1993.
2. The date the petition requesting the issuance of a regulation for use of the additive ("petition") was initially submitted with respect to the food additive under section 409 of

the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348): January 12, 1998. The applicant claims December 17, 1997, as the date the petition for neotame was initially submitted; however, FDA records indicate that the petition was submitted on January 12, 1998.

3. The date the petition became effective: July 9, 2002. FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on July 9, 2002.

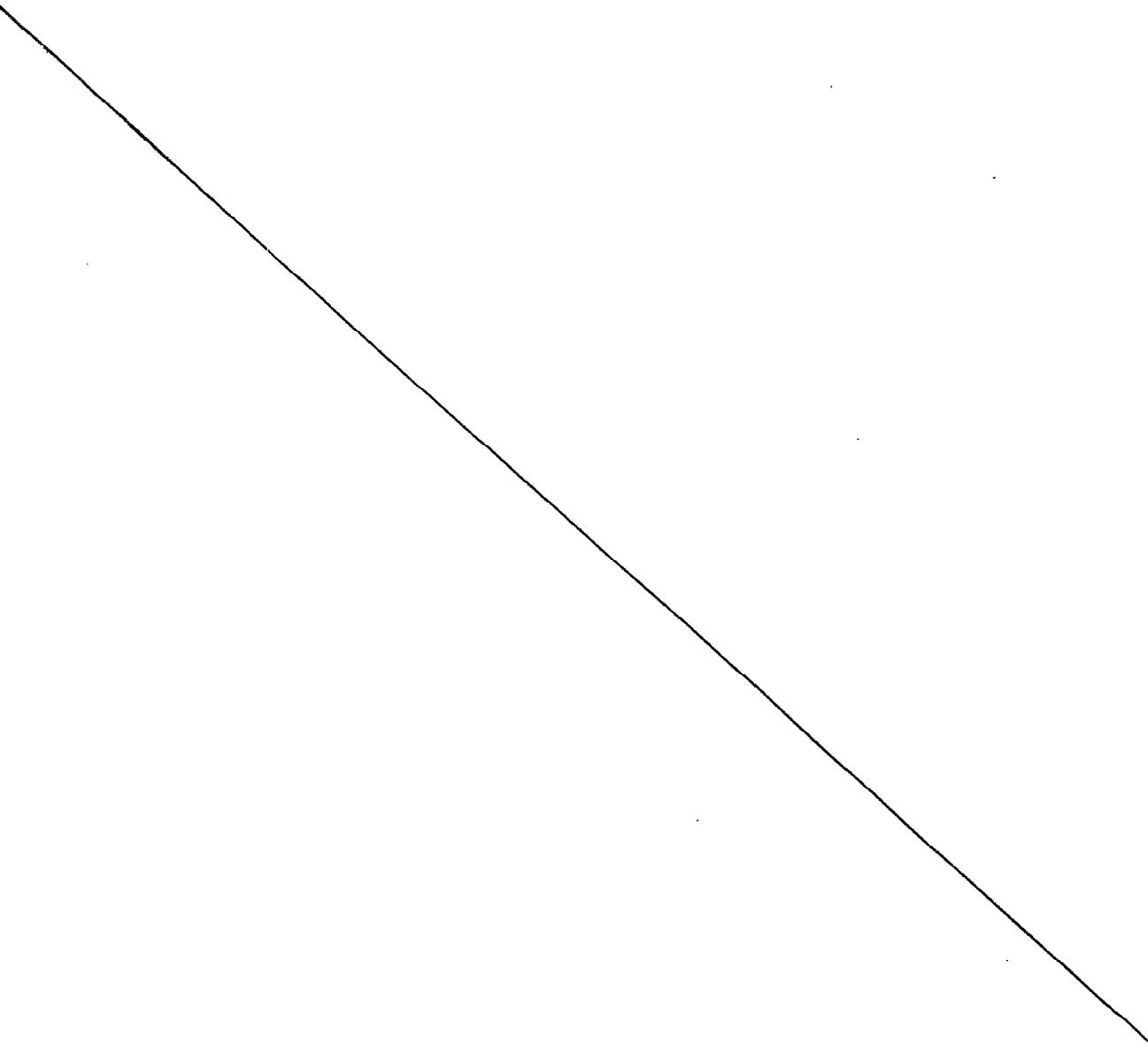
This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 973 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 or electronic comments and ask for a redetermination by [insert date 60 days after date of publication in the FEDERAL REGISTER]. 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 [insert date 180 days after date of publication in the FEDERAL REGISTER]. 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: June 21, 2004  
June 21, 2004.

Jane A. Axelrad

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Center for Drug Evaluation and Research

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