4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-E-1242; FDA-2012-E-1243]

Determination of Regulatory Review Period for Purposes of Patent Extension; CARBON DIOXIDE LASER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CARBON DIOXIDE LASER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the United States Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that food additive.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to http://www.regulations.gov at Docket No. FDA-2013-S-0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6257, Silver Spring, MD 20993-0002, 301-796-7900.

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 (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 food additives, the testing phase begins on the date when a major health or environmental effects test is begun and runs until a petition relying on the test and requesting the issuance of a regulation for use of the additive under section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348) is initially submitted to FDA. The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 of the FD&C Act is initially received. The approval phase continues until the regulation for the additive becomes effective or until commercial marketing is permitted (21 CFR 60.22). Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO 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)(1)(B).

FDA has amended the food additive regulations to provide for the safe use of CARBON DIOXIDE LASER for etching information on the surface of fresh, intact citrus fruit for commercial marketing as specified in 21 CFR 179.43. Subsequent to this approval, USPTO received patent term restoration applications for CARBON DIOXIDE LASER (U.S. Patent Nos. 5,660,747 and 5,897,797) from Durant Wayland, Inc., and the USPTO requested FDA's

assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 13, 2013, FDA advised the USPTO that this product had undergone a regulatory review period and that FDA's granting of the food additive petition for CARBON DIOXIDE LASER represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CARBON DIOXIDE LASER is 1,950 days. The applicant has not asserted a testing phase. All 1,950 days of the regulatory review period occurred during the approval phase. This period of time was derived from the following dates:

1. The date a major health or environmental effects test on the food additive was initiated: No date claimed. The applicant has not asserted a testing period.

2. The date the application was initially submitted with respect to the food additive under section 409 of the FD&C Act: February 9, 2007. FDA has determined that the food additive petition (FAP) for Carbon Dioxide Laser for Etching Food (FAP 7M4768) was submitted on February 9, 2007.

3. The date a regulation for use of the food additive became effective: June 11, 2012. FDA has verified the applicant's claim that FAP 7M4768 was granted through FDA's issuance of a responsive food additive regulation, effective June 11, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years 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) either electronic or written 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.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to http://www.regulations.gov, Docket No. FDA-2013-S-0610. Comments and petitions that have not been made publicly available on http://www.regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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