

4160-01-F

Display Date	9.28.98
Publication Date	9.21
Certifier	C. W. M. D. H.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0294]

Determination of Regulatory Review Period for Purposes of Patent Extension; Silvacote K

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Silvacote K 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 food additive.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brian J. Malkin,
Office of Health Affairs (HFY-20),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-827-6620.

OC98103

N I

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 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 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 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 Silvacote K (phosphorylated tall oil fatty acids). Silvacote K is indicated for use as pigment dispersants in polymeric films intended for use in contact with food. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Silvacote K (U.S. Patent No. 4,209,430) from SCM Chemicals, 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 October 21, 1997, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of Silvacote K 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 Silvacote K is 5,990 days. Of this time, 4,608 days occurred during the testing phase of the regulatory review period, 1,382 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 additive product was begun: March 30, 1980. The applicant claims November 6, 1992, as the date the test was begun. However, FDA records indicate that the

test was begun on March 30, 1980.

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 additive product under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348): November 9, 1992. The applicant claims November 6, 1992, as the date the petition for Silvacote K was initially submitted. However, FDA records indicate that the petition was submitted on November 9, 1992.

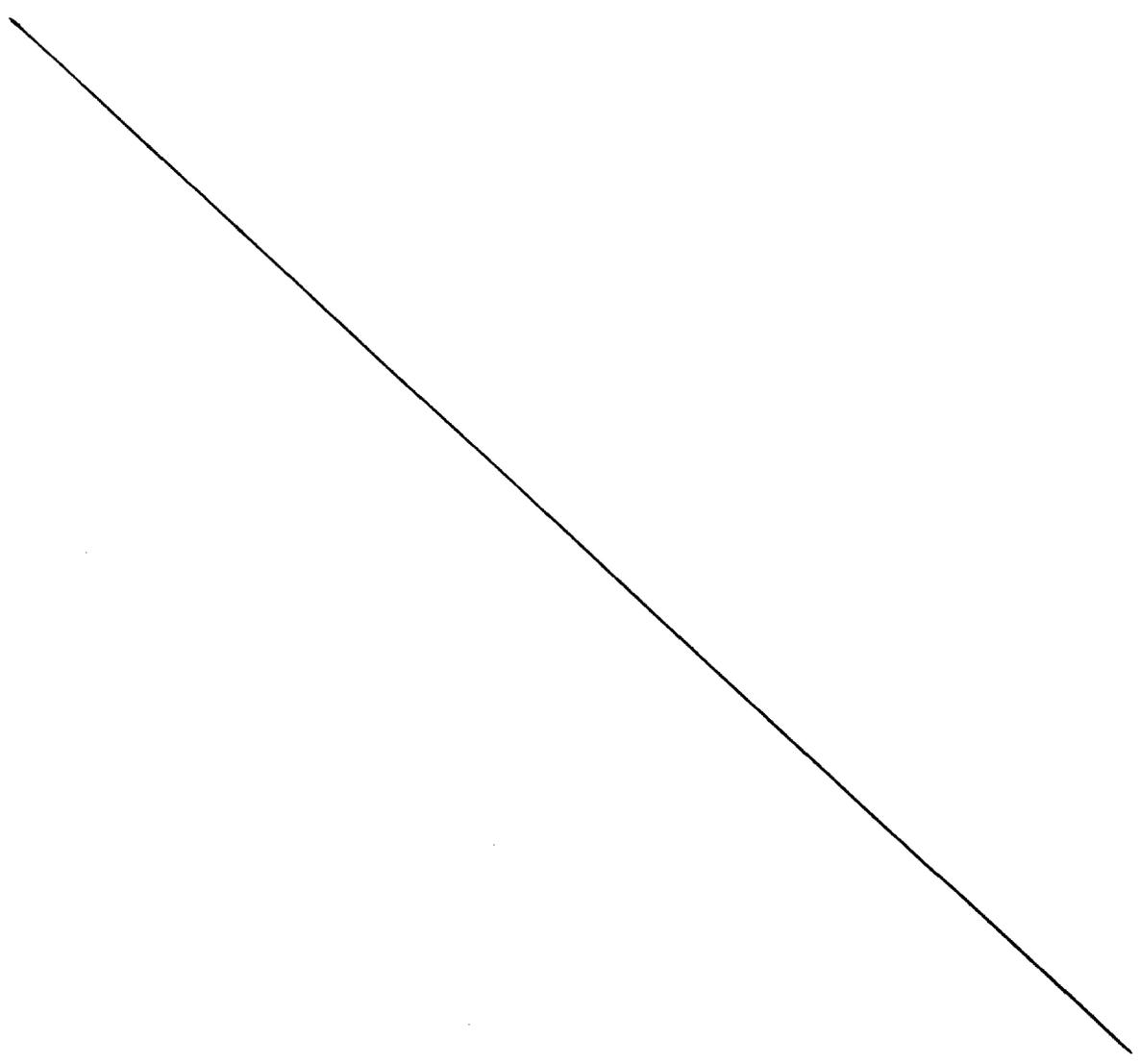
3. The date the petition became effective: August 21, 1996. FDA has verified the applicant's claim that the regulation for the food additive became effective on August 21, 1996.

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 1,385 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER), 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 (insert date 180 days after date of publication in the FEDERAL REGISTER), 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: 9/9/98
September 9, 1998

Thomas J. McGinnis

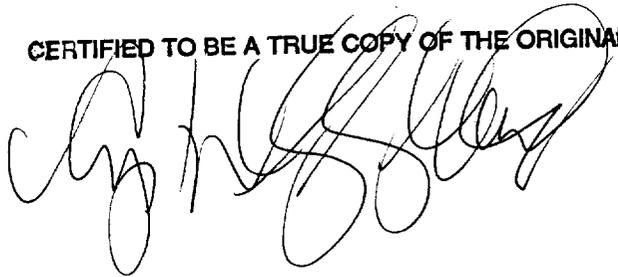
jt

Thomas J. McGinnis, R.Ph

Deputy Associate Commissioner

for Health Affairs

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



jt

OC98103