

**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.

**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 November 30, 1998, 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 March 29, 1999, 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: September 9, 1998.

**Thomas J. McGinnis,**

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98-25908 Filed 9-28-98; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 80G-0360]

**James Flett Organization, Inc.; Withdrawal of GRAS Affirmation Petition****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP C2182) proposing to affirm that the use of processed kraft paper and corrugated board as an ingredient in animal feeds is generally recognized as safe (GRAS).

**FOR FURTHER INFORMATION CONTACT:**

Sharon A. Benz, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6657.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of September 19, 1980 (45 FR 62552), FDA announced that a petition (GRASP C2182) had been filed by Flett Development Co. and Rumose Products Co., Divisions of the James Flett Organization, Inc., currently at 422 North Northwest Hwy., Park Ridge, IL 60068. This petition proposed to amend the GRAS regulations to affirm that use of processed kraft paper and corrugated board as an ingredient in animal feeds is GRAS. James Flett Organization, Inc., has now withdrawn the petition without prejudice to a future filing.

Dated: September 17, 1998.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 98-25915 Filed 9-28-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 98N-0473, 98P-0215, 98P-0216, 98P-0275, and 98P-0338]

### Medical Devices; Exemptions From Premarket Notification; Class II Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing an order denying four petitions requesting exemptions for five devices from the premarket notification requirements for certain class II devices. FDA is publishing this notice in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**EFFECTIVE DATE:** September 29, 1998.

#### **FOR FURTHER INFORMATION CONTACT:**

Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Statutory Background**

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA

classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no

longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

#### **II. Criteria for Exemption**

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." That guidance can be obtained through the World Wide Web on the CDRH home page at "http://www.fda.gov/cdrh" or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify "159" when prompted for the document shelf number.

#### **III. Petitions**

FDA has received the following petitions requesting an exemption from premarket notification for class II devices:

1. Sandhill Scientific Inc., 21 CFR 876.1725 *Gastrointestinal motility monitoring system*.
2. Welch Allyn, Inc., 21 CFR 886.1570 *Ophthalmoscope*.
3. Computerized Medical Systems, Inc., 21 CFR 892.5840 *Radiation therapy simulation system*, exemption requested only for Radiation Oncologist Data Entry Workstation.
4. Chemicon International Inc., 21 CFR 866.3175 *Cytomegalovirus serological reagents*, and 21 CFR 866.3900 *Varicella-zoster virus serological reagents*.

On July 21, 1998 (63 FR 39098), FDA published a notice announcing that