

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: February 16, 1999.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

[FR Doc. 99-5130 Filed 3-2-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99F-0298]

#### Asahi Denka Kogyo K.K.; Filing of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Asahi Denka Kogyo K.K. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aluminum, hydroxybis[2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxidato]- as a clarifying agent for polypropylene and polypropylene copolymers intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 9B4638) has been filed by Asahi Denka Kogyo K.K., 2-13, Shirahata 5-chome, Urawa City Saitama 336, Japan. The petition proposes to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the safe use of aluminum, hydroxybis[2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxidato]- as a clarifying agent for polypropylene and polypropylene copolymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 19, 1999.

**Laura M. Tarantino,**

*Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 99-5218 Filed 3-2-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98E-0843]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Singulair®

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

**ACTION:** Notice.

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

**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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product Singulair® (montelukast sodium). Singulair® is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 6 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Singulair® (U.S. Patent No. 5,565,473) from Merck & 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 December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Singulair® 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 Singulair is 2,090 days. Of this time, 1,725 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 3, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 3, 1992.
2. *The date the application was initially submitted with respect to the human drug product under section 505*

of the act. February 21, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Singulair® (NDA 20-829) was initially submitted on February 21, 1997.

3. *The date the application was approved:* February 20, 1998. FDA has verified the applicant's claim that NDA 20-829 was approved on February 20, 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 428 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, 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 August 30, 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: February 16, 1999.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

[FR Doc. 99-5132 Filed 3-2-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-484]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### *Type of Information Collection*

*Request:* Extension of a currently approved collection;

#### *Title of Information Collection:*

Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations in 42 CFR 410.38 and 424.5;

*Form No.:* HCFA-484 (OMB# 0938-0534);

*Use:* To determine if oxygen is reasonable and necessary pursuant to Medicare Statute, Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information including estimate length of need (# of months), diagnosis codes (ICD-9) and:

1. Results and date of the most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation tests.

2. The most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR within two days prior to discharge from an inpatient facility to home.

3. The most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation test performed at rest, during exercise, or during sleep.

4. Name and address of the physician/provider performing the most recent arterial blood gas PO<sub>2</sub> and/or oxygen saturation test.

5. If ordering portable oxygen, information regarding the patient's mobility within the home.

6. Identification of the highest oxygen flow rate (in liters per minute) prescribed.

7. If the prescribed liters per minute (LPM), as identified in item 6, are greater than 4 LPM, provide the results and date of the most recent arterial

blood gas PO<sub>2</sub> and/or oxygen saturation test taken on 4 LPM.

If the PO<sub>2</sub> = 56-59, or the oxygen saturation = 89%, then evidence of the beneficiary meeting at least one of the following criteria must be provided.

8. The patient having dependent edema due to congestive heart failure.

9. The patient having cor pulmonale or pulmonary hypertension, as documented by pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement.

10. The patient having a hematocrit greater than 56%.

Form HCFA-484 obtains all pertinent information and promotes national consistency in coverage determinations;

*Frequency:* Other (as needed);

*Affected Public:* Business or other for-profit, and Federal Government;

*Number of Respondents:* 500,000;

*Total Annual Responses:* 500,000;

*Total Annual Hours:* 50,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 23, 1999.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 99-5220 Filed 3-2-99; 8:45 am]

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