

concentrates and isolates from aqueous process streams for food processing.

FOR FURTHER INFORMATION CONTACT:

Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3077.

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 9A4659) has been filed by Life Technologies, Inc., 9800 Medical Center Dr., Rockville, MD 20850-3321. The petition proposes to amend the food additive regulations in § 173.25 *Ion-exchange resins* (21 CFR 173.25) to provide for the safe use of quaternary amine cellulose ion exchange resins in the isolation and purification of protein concentrates and isolates from aqueous process streams for food processing.

The agency has determined under 21 CFR 25.32(j) 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: April 19, 1999.

Alan M. Rulis,

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

[FR Doc. 99-10918 Filed 4-29-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90F-0018]

Rohm and Haas Co.; Withdrawal of Food Additive 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 food additive petition (FAP 0B4189) proposing that the food additive regulations be amended to provide for the expanded use of *n*-alkylglutarimide/acrylic copolymers as articles or components of articles intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 9, 1990 (55 FR 4690), FDA announced that a food additive petition (FAP 0B4189) had been filed by Rohm and Haas Co., Independence Mall West, Philadelphia, PA 19105 (currently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 177.1060 *n*-Alkylglutarimide/acrylic copolymers (21 CFR 177.1060) to provide for the expanded use of *n*-alkylglutarimide/acrylic copolymers as articles or components of articles intended for use in contact with food also under the conditions of use A, B, and C described in Table 2 of 21 CFR 176.170(c). Rohm and Haas Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 2, 1999.

Laura M. Tarantino,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-0488]

Determination of Regulatory Review Period for Purposes of Patent Extension; Gonal-F®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Gonal-F® 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 Gonal-F® (follitropin alpha/beta). Gonal-F® is indicated for the induction of ovulation and pregnancy in the anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure; and for the development of multiple follicles in the ovulatory patient participating in an Assisted Reproductive Technology (ART) program. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Gonal-F® (U.S. Patent No. 5,156,957) from Genzyme Corp., 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 14, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Gonal-F® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office