



SEP - 7 2006

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 4,600,706 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on May 13, 2004. The application was filed by May 13, 2004 on behalf of Arkion Life Sciences, the patent owner of record. Extension is sought based upon the premarket review under § 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a food additive known by the tradename NSURE® having the active ingredient natamycin was approved for commercial use and sale by the Food and Drug Administration (FDA) on April 13, 2004.

A determination has been made that U.S. Patent No. 4,600,706 is **NOT** eligible for patent term extension under 35 U.S.C. § 156. Although NSURE® was subject to a regulatory review period before the FDA, the approval does not constitute the first permitted commercial marketing or use as required by 35 U.S.C. § 156 (a)(5)(A). Accordingly, the application for patent term extension under 35 U.S.C. § 156 is **DISMISSED**.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that natamycin was previously approved for commercial marketing or use prior to the approval of NSURE®. In a letter dated July 24, 2006, FDA stated:

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period under section 409 of the Federal Food Drug and Cosmetic Act (21 USC 348) before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that NSURE® does not represent the first permitted commercial marketing or use of the food additive natamycin under 21 USC 348, the provisions of law under which the regulatory review period occurred.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 4,600,706 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product.

In view of the above, the term of U.S. Patent No. 4,600,706 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the **DISMISSED**.

Any correspondence with respect to this matter should be addressed as follows:

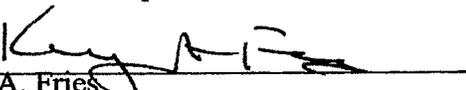
By mail: Mail Stop Patent Term Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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By FAX: (571) 273-0100

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755. E-mail inquiries should be directed to mary.till@uspto.gov.


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Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

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RE: NSURE®
FDA Docket No.: 2005E-0250