



JUN - 8 2000

Edward A. Meilman, Esq.  
Ostrolink, Faber, Gerb and Soffen  
1180 Avenue of the Americas  
New York, NY 10036In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,435,440

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,435,440, which claims the food additive SUCRALOSE, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of Two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of 63 Fed. Reg. 70411 (December 21, 1998). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,260 - 189) + 4,072 \\ &= 4,608 \text{ days}\end{aligned}$$

Since the regulatory review period began August 30, 1983, before the patent issued (March 6, 1984), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 30, 1983 to March 6, 1984 is 189 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156 (September 16, 1984). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.

4,435,440

Granted	March 6, 1984
Original Expiration Date	March 6, 2001
Applicant	Leslie Hough, et al.
Owner of Record	Tate & Lyle PLC
Title	Sweeteners
Classification	426/658
Product Trade Name	SUCRALOSE
Term Extended	Two years
Expiration Date of Extension	March 6, 2003

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

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703)872-9411  
Attn: Karin Tyson

By hand: Crystal Plaza Four, Suite 3C23  
2201 South Clark Place  
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



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for Patent Policy and Projects

cc: David T. Read  
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RE: SUCRALOSE  
FDA Docket No.: 95E-0788