

JUL 28 1998



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Daniel F. Nesbitt  
Patent Division  
The Procter & Gamble Company  
6071 Center Hill Avenue  
Cincinnati, OH 45224

In Re: Patent Term Extension  
Application for  
U.S. Patent No. Re. 34,617

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. Re. 34,617, which claims a method of use of the food additive OLEAN® (olestra), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years from the effective date of approval for commercial use.

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 Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 6, 1997 (62 Fed. Reg. 763). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (2,191) + 3,227 \\ &= 4,323 \text{ days} \end{aligned}$$

Since the regulatory review period began April 2, 1981, after the original patent's issue date (January 25, 1977) (the original patent number was U.S. Patent No. 4,005,196), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The extension determined above is limited by the two year limitation of 35 U.S.C. § 156(g)(6)(C), although pursuant to 35 U.S.C. § 156(d)(5)(E)(ii), the extension runs from the date the product received approval for commercial marketing or use, January 30, 1996.

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

|                 |   |                  |
|-----------------|---|------------------|
| U.S. Patent No. | : | Re. 34,617       |
| Granted         | : | May 24, 1994     |
| Approval Date   | : | January 30, 1996 |

|                              |   |   |
|------------------------------|---|---|
| Applicant                    | : | Ronald J. Jandacek et al.                                     |
| Owner of Record              | : | The Proctor and Gamble Company                                |
| Title                        | : | Vitaminized Compositions for<br>Treating Hypercholesterolemia |
| Classification               | : | 514/23  |
| Product Trade Name           | : | OLEAN® (olestra)  |
| Term Extended                | : | Two years   |
| Expiration Date of Extension | : | January 30, 1998  |

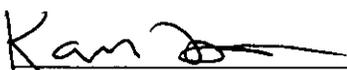
Any correspondence with respect to this matter should be addressed as follows:

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

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

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



Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
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Rockville, MD 20857

RE: OLEAN®  
FDA Docket No.: 96E-0080