



MAILED: June 6, 2002

Charles Van Horn
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1300 I Street NW
Washington DC 20005-3315

Re: Patent Term Extension
Application for
U.S. Patent No. 4,762,710

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,762,710, which claims the human drug product Certiva® (acellular purified pertussis toxoid), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,807 days.

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 Director will issue a certificate of extension, under seal, for a period of 1,807 days.

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 31, 2000 (65 Fed. Reg. 4614). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,542) + 1,036 \\ &= 1,807 \text{ days} \end{aligned}$$

Since the regulatory review period began July 10, 1991, after the patent issue date (August 9, 1988), 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.

Neither the 14 year exception of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above.

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

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|---|---|
| U.S. Patent No.: | 4,762,710 |
| Granted: | August 9, 1988 |
| Original Expiration Date ¹ : | June 16, 2006 |
| Applicant: | Ronald D. Sekura |
| Owner of Record: | The United States of America as represented by the Department of Health and Human Services |
| Title: | Novel Method of Preparing Toxoid by Oxidation |

¹Subject to the provisions of 35 U.S.C. § 41(b).

U.S. Patent No.:

4,762,710

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Classification: 424/92
Product Trade Name: Certiva® (acellular purified pertussis toxoid)
Term Extended: 1,807 days
Expiration Date of Extension: May 28, 2011

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

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

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

/s/

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read RE: Certiva® (acellular purified pertussis toxoid)
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 98E-1223
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852