§ 1.779 Calculation of patent term extension for a veterinary biological product.

(a) If a determination is made pursuant to §1.750 that a patent for a veterinary biological product is eligible for extension, the term shall be extended by the length of the regulatory review period for the product as determined by the Secretary of Agriculture, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(b) The term of the patent for a veterinary biological product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Agriculture. Under 35 U.S.C. 156(g)(5)(B), it is the sum of—

(1) The number of days in the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(d) The term of the patent as extended for a veterinary biological product will be determined by the Secretary of Agriculture. Under 35 U.S.C. 156(g)(5)(B), it is the sum of—

(1) The number of days in the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(3) If a major health or environmental effects test on the drug was initiated and no request was submitted for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act before November 16, 1988, by—

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date.

[54 FR 30381, July 20, 1989]
§ 1.780 Certificate or order of extension of patent term.

If a determination is made pursuant to §1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or an order granting interim extension under 35 U.S.C. 156(d)(5), will be issued to the applicant for the extension of the patent term. Such certificate or order will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate or order of extension will be published in the Official Gazette of the United States Patent and Trademark Office. Notification of the issuance of the order granting an interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the Official Gazette of the United States Patent and Trademark Office and in the Federal Register. No certificate of, or order granting, an extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations, the final determination made pursuant to §1.750 will indicate that no certificate or order will issue.

[65 FR 54680, Sept. 8, 2000]

§ 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

(a) Only one patent may be extended for a regulatory review period for any product (§1.720(h)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.