

(d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[54 FR 30381, July 20, 1989]

**§ 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 time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (§ 1.321).

(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, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period 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.

(d) The term of the patent as extended for a veterinary biological product will be determined by—

(1) Subtracting from the number of days determined by the Secretary of Agriculture to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section that were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Sec-

retary of Agriculture that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of the issuance of a license under the Virus-Serum-Toxin Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after November 16, 1988, by—

(i) Adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before November 16, 1988, and

(i) If no request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, by—

(A) Adding 5 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; or

(ii) If a request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, and the commercial marketing or use of the product was not approved 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

## § 1.780

## 37 CFR Ch. I (7-1-08 Edition)

(d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30382, 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.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the

patents are otherwise eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for extension pursuant to the requirements of this subpart, the certificate of extension of patent term will be issued on the application only if the patent owner or its agent is the holder of the regulatory approval granted with respect to the regulatory review period.

(d) An application for extension shall be considered complete and formal regardless of whether it contains the identification of the holder of the regulatory approval granted with respect to the regulatory review period. When an application contains such information, or is amended to contain such information, it will be considered in determining whether an application is eligible for an extension under this section. A request may be made of any applicant to supply such information within a non-extendable period of not less than one month whenever multiple applications for extension of more than one patent are received and rely upon the same regulatory review period. Failure to provide such information within the period for reply set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to § 1.750 and shall be regarded as part of that determination.

[60 FR 25618, May 12, 1995, as amended at 62 FR 53201, Oct. 10, 1997]

### **§ 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).**

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period