as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 515 of the Federal Food, Drug, and Cosmetic Act or the date a product development protocol was declared completed under section 515(f)(6) of the 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 September 24, 1984,

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

(ii) By 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 September 24, 1984, and

(i) If no clinical investigation on humans involving the device was begun or no product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug, and Cosmetic Act before September 24, 1984, by—

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

(B) By 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 clinical investigation on humans involving the device was begun or a product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug, and Cosmetic Act before September 24, 1984 and the commercial marketing or use of the product was not approved before September 24, 1984, by

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

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

§ 1.778 Calculation of patent term extension for an animal drug product.

(a) If a determination is made pursuant to § 1.750 that a patent for an animal drug 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 an animal drug will be extended by the length of the regulatory review period for the drug as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for an animal drug will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(4)(B), it is the sum of—

(1) The number of days in the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for the approved animal drug and ending on the date an application was initially submitted for such animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved animal drug under subsection (b) of section 512 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

(d) The term of the patent as extended for an animal drug will be determined by—

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services 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 Secretary of Health and Human Services 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 approval of the application under section 512 of the Federal Food, Drug, and Cosmetic 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 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 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 major health or environmental effects test was initiated or a request for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act was submitted before November 16, 1988, and the application for commercial marketing or use of the animal drug 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 (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