

any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

[54 FR 30379, July 20, 1989]

**§ 1.720 Conditions for extension of patent term.**

The term of a patent may be extended if:

(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;

(b) The term of the patent has never been previously extended, except for extensions issued pursuant to §§ 1.701, 1.760, or § 1.790;

(c) An application for extension is submitted in compliance with § 1.740;

(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

(e) The product has received permission for commercial marketing or use and—

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regu-

latory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent, including any interim extension issued pursuant to § 1.790, has not expired before the submission of an application in compliance with § 1.741; and

(h) No other patent term has been extended for the same regulatory review period for the product.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989; 65 FR 54679, Sept. 8, 2000]

**§ 1.730 Applicant for extension of patent term; signature requirements.**

(a) Any application for extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of § 1.740.

(b) If the application is submitted by the patent owner, the application must be signed either by:

(1) The patent owner in compliance with § 3.73(b) of this chapter; or

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(2) A registered practitioner on behalf of the patent owner.

(c) If the application is submitted on behalf of the patent owner by an agent of the patent owner (*e.g.*, a licensee of the patent owner), the application must be signed by a registered practitioner on behalf of the agent. The Office may require proof that the agent is authorized to act on behalf of the patent owner.

(d) If the application is signed by a registered practitioner, the Office may require proof that the practitioner is authorized to act on behalf of the patent owner or agent of the patent owner.

[65 FR 54679, Sept. 8, 2000]

### **§ 1.740 Formal requirements for application for extension of patent term; correction of informalities.**

(a) An application for extension of patent term must be made in writing to the Commissioner. A formal application for the extension of patent term must include:

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics;

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred;

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred;

(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

(5) A statement that the application is being submitted within the sixty day

period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted;

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration;

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings;

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent;

(9) A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:

(i) The approved product, if the listed claims include any claim to the approved product;

(ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and

(iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product;

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product:

(A) The effective date of the investigational new drug (IND) application and the IND number;

(B) The date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number; and

(C) The date on which the NDA was approved or the Product License issued;