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.

§ 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 Director. 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;

(ii) For a patent claiming a new animal drug:

(A) The date a major health or environmental effects test on the drug was...
§ 1.741 Complete application given a filing date; petition procedure.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Office or filed pursuant to the procedures set forth in § 1.8 or § 1.10. A complete application must include:

(1) An identification of the approved product;

(b) The application under this section must be accompanied by two additional copies of such application (for a total of three copies).

(c) If an application for extension of patent term is informal under this section, the Office will so notify the applicant. The applicant has two months from the mail date of the notice, or such time as is set in the notice, within which to correct the informality. Unless the notice indicates otherwise, this time period may be extended under the provisions of § 1.136.