

§ 1.741

(17) An oath or declaration as set forth in paragraph (b) of this section.

(b) Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

(1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.

(2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to § 1.710;

(4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

(c) If any application for extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to § 1.181, § 1.182 or § 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

[54 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989; 56 FR 65155, Dec. 13, 1991]

§ 1.741 Filing date of application.

(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 Patent and Trademark Office or filed pursuant to the "Certificate of Mailing or Transmission" procedures of 37 CFR 1.8 or "Express Mail" provisions of 37 CFR

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1.10. A complete application shall include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Commissioner to determine under 35 U.S.C. 156 subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If any application submitted pursuant to this section is held to be incomplete, applicant may seek to have this holding reviewed under § 1.181.

[52 FR 9394, Mar. 24, 1987, as amended at 59 FR 54503, Oct. 22, 1993; 61 FR 64028, Dec. 3, 1996]

§ 1.750 Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed in compliance with § 1.740 or § 1.790. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with § 1.740,