(3) Applicant means any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking patent term restoration.


(5) Clinical investigation or study means any experiment that involves a test article and one or more subjects and that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 512(j), or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to FDA under those sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 regarding nonclinical laboratory studies.

(6) Color additive means any substance that meets the definition in section 201(t) of the Act and which is subject to premarketing approval under section 721 of the Act.

(7) Due diligence petition means a petition submitted under §60.30(a).

(8) FDA means the Food and Drug Administration.

(9) Food additive means any substance that meets the definition in section 201(s) of the Act and which is subject to premarketing approval under section 409 of the Act.

(10) Human drug product means the active ingredient of a new drug or human biologic product (as those terms are used in the Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(11) Marketing applicant means any person who submits an application for premarketing approval by FDA under:
   (i) Section 505(b) of the Act or section 351 of the Public Health Service Act (human drug products);
   (ii) Section 515 of the Act (medical devices);
   (iii) Section 409 or 721 of the Act (food and color additives); or
   (iv) Section 512 of the Act (animal drug products).

(12) Marketing application means an application for:
   (i) Human drug products submitted under section 505(b) of the Act or section 351 of the Public Health Service Act;
   (ii) Medical devices submitted under section 515 of the Act;
   (iii) Food and color additives submitted under section 409 or 721 of the Act; or

(13) Medical device means any article that meets the definition in section 201(h) of the Act and which is subject to premarketing approval under section 515 of the Act.

(14) Product means a human drug product, animal drug product, medical device, food additive, or color additive, as those terms are defined in this section.

(15) PTO means the United States Patent and Trademark Office.

(16) Animal drug product means the active ingredient of a new animal drug (as that term is used in the Act) that is not primarily manufactured using recombinant deoxyribonucleic acid (DNA), recombinant ribonucleic acid (RNA), hybridoma technology, or other processes involving site-specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

§ 60.10 FDA assistance on eligibility.

(a) Upon written request from the U.S. Patent and Trademark Office, FDA will assist the U.S. Patent and Trademark Office in determining whether a patent related to a product is eligible for patent term restoration as follows:
   (1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;
   (2) For human drug products, food additives, color additives, and medical
§ 60.20 FDA action on regulatory review period determinations.

(a) FDA will consult its records and experts to verify the dates contained in the application and to determine the length of the product’s regulatory review period under §60.22. The application shall contain information relevant to the determination of the regulatory review period as stated in the “Guidelines for Extension of Patent Term Under 35 U.S.C. 156” published on October 9, 1984, in PTO’s Official Gazette and as required by 37 CFR chapter I.

(b) After determining the length of the regulatory review period, FDA will notify PTO in writing of its determination, send a copy of this determination to the applicant, and file a copy of the determination in the docket established for the application in FDA’s Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(c) FDA will also publish the regulatory review period determination in the Federal Register. The notice will include the following:

1. The name of the applicant;
2. The trade name and generic name (if applicable) of the product;
3. The number of the patent for which an extension of the term is sought;
4. The approved indications or uses for the product;
5. An explanation of any discrepancies between the dates in the application and FDA records;
6. Where appropriate, an explanation that FDA has no record in which to review the date(s) contained in the application; and
7. The regulatory review period determination, including a statement of the length of the testing and approval phases and the dates used in calculating each phase.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994]

§ 60.22 Regulatory review period determinations.

In determining a product’s regulatory review period, which consists of the sum of the lengths of a testing