

## § 60.1

## 21 CFR Ch. I (4–1–12 Edition)

### Subpart C—Regulatory Review Period Determinations

- 60.20 FDA action on regulatory review period determinations.
- 60.22 Regulatory review period determinations.
- 60.24 Revision of regulatory review period determinations.
- 60.26 Final action on regulatory review period determinations.
- 60.28 Time frame for determining regulatory review periods.

### Subpart D—Due Diligence Petitions

- 60.30 Filing, format, and content of petitions.
- 60.32 Applicant response to petition.
- 60.34 FDA action on petitions.
- 60.36 Standard of due diligence.

### Subpart E—Due Diligence Hearings

- 60.40 Request for hearing.
- 60.42 Notice of hearing.
- 60.44 Hearing procedures.
- 60.46 Administrative decision.

AUTHORITY: 21 U.S.C. 348, 355, 360e, 360j, 371, 379e; 35 U.S.C. 156; 42 U.S.C. 262.

SOURCE: 53 FR 7305, Mar. 7, 1988, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 60 appear at 68 FR 24879, May 9, 2003.

### Subpart A—General Provisions

#### § 60.1 Scope.

(a) This part sets forth procedures and requirements for the Food and Drug Administration's review of applications for the extension of the term of certain patents under 35 U.S.C. 156. Patent term restoration is available for certain patents related to drug products (as defined in 35 U.S.C. 156(f)(2)), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. Food and Drug Administration actions in this area include:

(1) Assisting the United States Patent and Trademark Office in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to the Food

and Drug Administration's regulatory review period determinations; and

(4) Conducting hearings to review initial Food and Drug Administration findings on due diligence challenges.

(b) References in this part to the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56261, Nov. 27, 1992]

#### § 60.2 Purpose.

(a) The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications. To achieve this purpose, the regulations are intended to:

(1) Facilitate determinations of patent term restoration eligibility and regulatory review period length, and

(2) Ensure that parties interested in due diligence challenges will have an opportunity to participate in that process, including informal hearings.

(b) The regulations are intended to complement those promulgated by the United States Patent and Trademark Office to implement those parts of the law which are under that agency's jurisdiction. These regulations shall be construed in light of these objectives.

#### § 60.3 Definitions.

(a) The definitions contained in 35 U.S.C. 156 apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) The term *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201–901, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 301–392)).

(2) *Active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(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.

(4) *Application* means an application for patent term restoration submitted under 35 U.S.C. 156.

(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 non-clinical 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

(iv) Animal drug products submitted under section 512 of the Act.

(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.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56261, Nov. 27, 1992; 64 FR 399, Jan. 5, 1999]

## Subpart B—Eligibility Assistance

### § 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