

§ 60.10

21 CFR Ch. I (4–1–04 Edition)

(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 devices, determining whether the permission for commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product either:

(i) Under the provision of law under which the regulatory review period occurred; or

(ii) Under the process claimed in the patent when the patent claims a method of manufacturing the product that primarily uses recombinant deoxyribonucleic acid (DNA) technology in the manufacture of the product;

(3) For animal drug products, determining whether the permission for commercial marketing or use of the product after the regulatory review period:

(i) Is the first permitted commercial marketing or use of the product; or

(ii) Is the first permitted commercial marketing or use of the product for administration to a food-producing animal, whichever is applicable, under the provision of law under which the regulatory review period occurred;

(4) Informing the U.S. Patent and Trademark Office whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use, or, if the product is an animal drug approved for use in a food-producing animal, verifying whether the application was filed within 60 days of the first approval for marketing or use in a food-producing animal; and

(5) Providing the U.S. Patent and Trademark Office with any other information relevant to the U.S. Patent and Trademark Office's determination of whether a patent related to a product is eligible for patent term restoration.

(b) FDA will notify the U.S. Patent and Trademark Office of its findings in writing, send a copy of this notification to the applicant, and file a copy of the notification in the docket established for the application in FDA's Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[57 FR 56261, Nov. 27, 1992]

Subpart C—Regulatory Review Period Determinations

§ 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