

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 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