§ 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.

§ 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