§ 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 the notification 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.

§ 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 phase and an approval phase, FDA will review the information in each application using the following definitions of the testing phase and the approval phase for that class of products.

(a) For human drugs:

(1) The testing phase begins on the date an exemption under section 505(i) of the Act becomes effective (or the date an exemption under former section 507(d) of the Act became effective) for the approved human drug product and ends on the date a marketing application under section 351 of the Public Health Service Act or section 505 of the Act is initially submitted to FDA (or was initially submitted to FDA under former section 507 of the Act), and

(2) The approval phase begins on the date a marketing application under section 351 of the Public Health Service Act or section 505(b) of the Act is initially submitted to FDA (or was initially submitted under former section 507 of the Act) and ends on the date the application is approved.