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(d) The 60-day period shall begin when FDA receives a manufacturer's submission, including, where applicable, a certification statement or an application for an exemption.

§ 99.203 Request to extend the time for completing planned studies.

(a) A manufacturer may request, prior to or at the time of making a submission to FDA under § 99.201, that FDA extend the 36-month time period for completing the studies and submitting a supplemental application for the new use that is the subject of the information to be disseminated. Such request must set forth the reasons that such studies cannot be completed and submitted in a supplemental application within 36 months.

(b) A manufacturer who has certified that it will complete the studies necessary to submit a supplemental application for a new use within a specified period of time from the date that dissemination of information under this part can begin under § 99.201(a)(4)(ii), but later finds that it will be unable to complete such studies and submit a supplemental application within that time period may request an extension of time from FDA. The manufacturer, in its request for extension, shall identify the product, the new use, and shall:

(1) Describe the study or studies that cannot be completed on time and explain why the study or studies cannot be completed on time;

(2) Describe the current status of the incomplete study or studies and summarize the work conducted, including the dates on which principal events concerning the study or studies occurred; and

(3) Estimate the additional time needed to complete the studies and submit a supplemental application. The requested extension shall not exceed an additional 24 months.

(c) The manufacturer shall send three copies of the request for extension to the same FDA office that received the manufacturer's initial submission and certification statement. The outside of the envelope shall be marked as ''Request for Time Extension—Dissemination of Information on an Unapproved Use.''

§ 99.205 Application for exemption from the requirement to file a supplemental application.

(a) In certain circumstances, described in paragraph (b) of this section, a manufacturer may submit an application for an exemption from the requirement to submit a supplemental application for a new use for purposes of disseminating information on that use.

(b) The manufacturer's application for an exemption shall identify the basis for the proposed exemption and shall include materials demonstrating that it would be economically prohibitive or that it would be unethical to conduct the studies necessary to submit a supplemental application for the new use.

(1) If the basis for the manufacturer's application for exemption is that it would be economically prohibitive to incur the costs necessary to submit a supplemental application for a new use, the manufacturer shall, at a minimum, provide:

(i) Evidence explaining why existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated, are not adequate to support the submission of a supplemental application for the new use. Such evidence shall include an analysis of all data relevant to the safety and effectiveness of the use, a summary of those data, and any documentation resulting from prior discussions with the agency concerning the adequacy of the existing data; and

(ii) Evidence demonstrating that the cost of the study or studies for the new use reasonably exceeds the expected revenue from the new use minus the costs of goods sold and marketing and administrative expenses attributable to the new use of the product. Such evidence shall include:

(A) A description of the additional studies that the manufacturer believes are necessary to support the submission of a supplemental application for the new use, including documentation from prior discussions, if any, with the agency concerning the studies that would be needed, and an estimate of the projected costs for such studies;

(B) The expected patient population for the new use;