

moved forward 1 day for each day, after mailing date of the request, taken by the petitioner to submit the information and/or sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(a) *Extension of time for studying petitions.* If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical laboratory study contained in the petition, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. If clinical investigations involving human subjects are involved, additional information or data submitted in support of filed petitions shall include statements regarding each such clinical investigation from which the information or data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed

consent set forth in part 50 of this chapter.

(c) *Withdrawal of petitions without prejudice.* (1) In some cases the Commissioner may notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(2) At any time before the order provided for in § 71.20 has been forwarded to the FEDERAL REGISTER for publication the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 60021, Dec. 22, 1978; 46 FR 8952, Jan. 27, 1981; 50 FR 7491, Feb. 22, 1985]

§ 71.15 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.