Food and Drug Administration, HHS

§ 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.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA or, if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

[42 FR 15639, Mar. 22, 1977, as amended at 64 FR 400, Jan. 5, 1999]

§ 71.4 Samples; additional information.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, and any additional information needed to clarify a submitted method or other aspect of a petition at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the color additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 721(d)(1) of the act shall be 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the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

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[42 FR 15639, Mar. 22, 1977, as amended at 64 FR 400, Jan. 5, 1999]
§ 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.
   ii. Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.
4. A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in §20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.
5. An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in §20.61 of this chapter.
6. All records showing the Food and Drug Administration's testing of or action on a particular lot of a certifiable color additive.

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