

## § 571.6

of the food additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 409(c)(2) of the act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the 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the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each study, 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.

[41 FR 38647, Sept. 10, 1976, as amended at 42 FR 15675, Mar. 22, 1977; 50 FR 7518, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 8583, Mar. 19, 1987; 57 FR 6476, Feb. 25, 1992; 62 FR 40600, July 29, 1997]

### § 571.6 Amendment of petition.

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 such study, 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 or the noncompliance.

[41 FR 38647, Sept. 10, 1976, as amended at 50 FR 7518, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985]

## 21 CFR Ch. I (4-1-03 Edition)

### § 571.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will 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.

(b) At any time before the order provided for in § 571.100(a) 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.

## Subpart B—Administrative Actions on Applications

### § 571.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the act), a regulation prescribing the conditions under which the food additive used may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and prior to the forwarding of the order to the FEDERAL REGISTER for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) 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.

**§ 571.102 Effective date of regulation.**

A regulation published in accordance with § 571.100(a) shall become effective upon publication in the FEDERAL REGISTER.

**§ 571.110 Procedure for objections and hearings.**

Objections and hearings relating to food additive regulations under section 409(c), (d), or (h) of the act shall be governed by part 12 of this chapter.

[42 FR 4717, Jan. 25, 1977, as amended at 42 FR 15676, Mar. 22, 1977]

**§ 571.115 Application of the cancer clause of section 409 of the act.**

Food additives intended for use as an ingredient in food for animals that are raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

[52 FR 49588, Dec. 31, 1987]

**§ 571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.**

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data

shall be furnished in the form specified in § 571.1 for submitting petitions.

[42 FR 4717, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977]

**PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS**

**Subpart A [Reserved]**

**Subpart B—Food Additive Listing**

Sec.	
573.120	Acrylamide-acrylic acid resin.
573.130	Aminoglycoside 3'-phospho-transferase II.
573.140	Ammoniated cottonseed meal.
573.160	Ammoniated rice hulls.
573.180	Anhydrous ammonia.
573.200	Condensed animal protein hydrolysate.
573.220	Feed-grade biuret.
573.225	1,3-Butylene glycol.
573.240	Calcium periodate.
573.260	Calcium silicate.
573.280	Feed-grade calcium stearate and sodium stearate.
573.300	Choline xanthate.
573.310	Crambe meal, heat toasted.
573.320	Diammonium phosphate.
573.340	Diatomaceous earth.
573.360	Disodium EDTA.
573.380	Ethoxyquin in animal feeds.
573.400	Ethoxyquin in certain dehydrated forage crops.
573.420	Ethyl cellulose.
573.440	Ethylene dichloride.
573.450	Fermented ammoniated condensed whey.
573.460	Formaldehyde.
573.480	Formic acid.
573.500	Condensed, extracted glutamic acid fermentation product.
573.520	Hemicellulose extract.
573.530	Hydrogenated corn syrup.
573.540	Hydrolyzed leather meal.
573.560	Iron ammonium citrate.
573.580	Iron-choline citrate complex.
573.600	Lignin sulfonates.
573.620	Menadione dimethylpyrimidinol bisulfite.
573.625	Menadione nicotinamide bisulfite.
573.640	Methyl esters of higher fatty acids.
573.660	Methyl glucoside-coconut oil ester.
573.680	Mineral oil.
573.700	Sodium nitrite.
573.720	Petrolatum.
573.740	Odorless light petroleum hydrocarbons.
573.750	Pichia pastoris dried yeast.
573.760	Poloxalene.
573.780	Polyethylene.
573.800	Polyethylene glycol (400) mono- and diolate.