

the study was not conducted in compliance with such regulations, a brief statement of the reason for the non-compliance.

[50 FR 7492, Feb. 22, 1985, as amended at 50 16668, Apr. 26, 1985]

§ 171.7 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 refileing, the time limitation will begin to run anew from the date of refileing.

(b) At any time before the order provided for in § 171.100(a) has been forwarded to the FEDERAL REGISTER for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refileing the time limitation will begin to run anew.

§ 171.8 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate or that may be expected to migrate into food at negligible levels may be reviewed under § 170.39 of this chapter. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in § 170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

[60 FR 36596, July 17, 1995]

Subpart B—Administrative Actions on Applications

§ 171.100 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 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.

§ 171.102 Effective date of regulation.

A regulation published in accordance with § 171.100(a) shall become effective upon publication in the FEDERAL REGISTER.

§ 171.110 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 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

§ 171.130 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 §§ 171.1 and 171.100 for submitting petitions.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Subpart A—General Provisions

Sec.

172.5 General provisions for direct food additives.

Subpart B—Food Preservatives

172.105 Anoxomer.
 172.110 BHA.
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 172.120 Calcium disodium EDTA.
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 172.150 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.
 172.155 Natamycin (pimaricin).
 172.160 Potassium nitrate.
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172.210 Coatings on fresh citrus fruit.
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 172.225 Methyl and ethyl esters of fatty acids produced from edible fats and oils.
 172.230 Microcapsules for flavoring substances.
 172.235 Morpholine.
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 172.270 Sulfated butyl oleate.

172.275 Synthetic paraffin and succinic derivatives.

172.280 Terpene resin.

Subpart D—Special Dietary and Nutritional Additives

172.310 Aluminum nicotinate.
 172.315 Nicotinamide-ascorbic acid complex.
 172.320 Amino acids.
 172.325 Bakers yeast protein.
 172.330 Calcium pantothenate, calcium chloride double salt.
 172.335 D-Pantothenamide.
 172.340 Fish protein isolate.
 172.345 Folic acid (folacin).
 172.350 Fumaric acid and salts of fumaric acid.
 172.365 Kelp.
 172.370 Iron-choline citrate complex.
 172.372 N-Acetyl-L-methionine.
 172.375 Potassium iodide.
 172.385 Whole fish protein concentrate.
 172.395 Xylitol.
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Subpart E—Anticaking Agents

172.410 Calcium silicate.
 172.430 Iron ammonium citrate.
 172.480 Silicon dioxide.
 172.490 Yellow prussiate of soda.

Subpart F—Flavoring Agents and Related Substances

172.510 Natural flavoring substances and natural substances used in conjunction with flavors.
 172.515 Synthetic flavoring substances and adjuvants.
 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.
 172.530 Disodium guanylate.
 172.535 Disodium inosinate.
 172.540 DL-Alanine.
 172.560 Modified hop extract.
 172.575 Quinine.
 172.580 Safrole-free extract of saffrafras.
 172.585 Sugar beet extract flavor base.
 172.590 Yeast-malt sprout extract.

Subpart G—Gums, Chewing Gum Bases and Related Substances

172.610 Arabinogalactan.
 172.615 Chewing gum base.
 172.620 Carrageenan.
 172.623 Carrageenan with polysorbate 80.
 172.626 Salts of carrageenan.
 172.655 Furcelleran.
 172.660 Salts of furcelleran.
 172.665 Gellan gum.
 172.695 Xanthan gum.