Food and Drug Administration, HHS

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 REG-ISTER, 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) The regulation shall describe the conditions under which the substance may be safely used in any meat product, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*).

(c) 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.

 $[42\ {\rm FR}\ 14489,\ {\rm Mar.}\ 15,\ 1977,\ {\rm as}\ {\rm amended}\ {\rm at}\ 65\ {\rm FR}\ 51763,\ {\rm Aug.}\ 25,\ 2000]$

§171.102 Effective date of regulation.

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

§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.

 $[42\ {\rm FR}\ 14491,\ {\rm Mar.}\ 15,\ 1977,\ {\rm as}\ {\rm amended}\ {\rm at}\ 42\ {\rm FR}\ 15674,\ {\rm Mar.}\ 22,\ 1977]$

PART 172—FOOD ADDITIVES PER-MITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMP-TION

Subpart A—General Provisions

Sec.

172.5 General provisions for direct food additives.

Subpart B—Food Preservatives

- 172.105 Anoxomer.
- 172.110 BHA.
- 172.115 BHT.
- 172.120 Calcium disodium EDTA.
- 172.130 Dehydroacetic acid.

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