

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 71, 170, and 171 be amended as follows:

PART 71—COLOR ADDITIVE PETITIONS

1. The authority citation for 21 CFR part 71 continues to read as follows:

Authority: Secs. 201, 402, 409, 501, 505, 506, 507, 510, 512-516, 518-520, 601, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 351, 355, 356, 357, 360, 360b-360f, 360h-360j, 361, 371, 379e, 381); secs. 215, 351 of the Public Health Service Act (42 U.S.C. 216, 262).

2. Section 71.1 is amended in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A., and by adding new paragraph (j) to read as follows:

§ 71.1 Petitions.

* * * * *

(c) * * *

Attached hereto in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

* * * * *

(j)(1) If intended uses of the color additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(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.

3. Section 71.20 is amended by adding new paragraph (a)(3) to read as follows:

§ 71.20 Publication of regulation.

* * * * *

(a) * * *

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA)(21 U.S.C. 601 et seq.) or Poultry Products Inspection (PPIA)(21 U.S.C. 451 et seq.) for which the color additive has been found suitable and for which it may safely be employed.

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PART 170—FOOD ADDITIVES

4. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

5. Section 170.35 is amended by redesignating paragraphs (c)(3) through (c)(6) as paragraphs (c)(4) through (c)(7), respectively, and by adding new paragraph (c)(3) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) * * *

(3)(i) If intended uses of the substance include uses in meat, meat food product, or poultry product subject to regulation by the U. S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(ii) 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.

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PART 171—FOOD ADDITIVE PETITIONS

6. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

7. Section 171.1 is amended in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A., and by adding new paragraph (n) to read as follows:

§ 171.1 Petitions.

* * * * *

(c) * * *

Attached hereto, in triplicate (quadruplicate, if intended uses include use

in meat, meat food product, or poultry product), and constituting a part of this petition, are the following:

* * * * *

(n) (1) If intended uses of the food additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(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.

8. Section 171.100 is amended by redesignating paragraph (b) as paragraph (c) and by adding new paragraph (b) to read as follows:

§ 171.100 Regulation based on petition.

* * * * *

(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.).

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Dated: October 11, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-31491 Filed 12-26-95; 3:37 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 165, 166, 168, and 169

[Docket No. 95N-0294]

Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.