DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 71, 170, and 171

[Docket No. 95N–0220]

RIN 0910–AA66

Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the review of petitions for the approval of food and color additives and substances generally recognized as safe (GRAS) to provide for joint review of such petitions by the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), when meat or poultry product uses are proposed. By agreement between USDA and FDA, such listings would eliminate the need for a separate FSIS rulemaking to allow the use in meat and poultry products of FDA-approved substances.

DATES: Written comments by March 14, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: George H. Pauli, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA, under the Federal Food, Drug, and Cosmetic Act (the act), is responsible for regulating foods generally. FSIS, under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), regulates products consisting wholly or in part of meat or poultry.

Over the years, FDA has generally deferred to FSIS in matters concerning the regulation of meat and meat food products (hereinafter referred to collectively as meat products) and poultry products, despite FDA's broad jurisdiction over all food. This approach is consistent with the proposition that in cases of possible jurisdictional overlap, an agency with a broad grant of statutory authority will normally defer to an agency with a more specific grant of authority. FSIS has primary jurisdiction over meat and poultry products and is tasked with ensuring that all those products are inspected before they are permitted in commerce. FSIS regulations and guidelines govern all aspects of meat and poultry products that are subject to such inspection. These include regulations and guidance on substances that may be added to those products.

Since the 1958 Food Additives Amendment to the act, FSIS has come to rely on FDA in most matters concerning the safety of food and color additives and other substances that may be used in meat and poultry products. FDA regulates food additives and color additives through a premarket approval system established respectively by sections 409 and 721 of the act (21 U.S.C. 348 and 379e). FDA has developed the scientific staff, the institutional expertise, and the regulatory structure to ensure the safety of substances that may be added to foods. The act requires that both food additives and color additives be shown to be safe before marketing (21 U.S.C. 348(c)(3) and 379e(b)(4)). In addition, FDA may not approve any use of a food additive that would ''promote deception of the consumer * * * or would otherwise result in adulteration or misbranding of food * * * '' (21 U.S.C. 348(c)(3)(B)). Similarly, a color additive must also be shown to be suitable for its intended use (21 U.S.C. 379e(b)(1)).

Over the years, the two agencies have cooperated on food ingredient issues on an as-needed, substance-specific, and case-by-case basis. Nonetheless, because of their different regulatory needs, the two agencies' regulations governing the use of these substances in foods are cast in formats and terms that are not fully consistent with one another. This absence of consistency causes difficulty and inconvenience to persons who need to refer to both agencies' regulations on approved substances and substance uses.

Furthermore, it is not clear from the regulations where one agency's jurisdiction ends and the other's begins. The public frequently sends FSIS requests for approval of the use of substances in food that must be referred to FDA, and sends FDA requests involving meat or poultry uses that must be referred to FSIS.

Finally, FSIS's current regulations require that those seeking approval of a substance for use in or on meat or poultry products first establish that the substance is safe for the intended use under section 409 or section 721 of the act, and second, that it is suitable for the intended use under the FMIA or PPIA (9 CFR 318.7(a) and 381.147(f)). As a result, both agencies conduct separate, sequential reviews and rulemakings before a new meat or poultry use can be permitted. Many years can elapse between the time a manufacturer petitions FDA for the approval of a food additive or a color additive under the act and the appearance in FSIS's regulations of approval for meat and poultry uses.

FDA and FSIS have also concluded that their respective regulations concerning food and color additives and other substances that may be added to meat and poultry products should be more consistent with one another and easier to use and access.

II. The Proposal

This proposed rule, together with an FSIS proposed rule appearing elsewhere in this issue of the Federal Register, would require a single petition, joint reviews, and a single rulemaking procedure to replace the current time consuming, duplicative, sequential rulemaking procedures governing the use in meat or poultry products of food additives, color additives, and GRAS substances. It is intended to clarify the two agencies' responsibilities and regulatory interests. Future FSIS listings for meat and poultry uses would be harmonized with those of FDA and incorporated into FDA's regulations in Title 21 of the Code of Federal Regulations (CFR), providing a basis for the eventual elimination of FSIS's separate listings from Title 9 CFR.

Substances would be authorized for use in products under the jurisdiction of FSIS on the basis of FDA's regulations permitting such uses. For a substance *not* authorized for meat or poultry use under existing FDA regulations, only one petition for rulemaking—to FDA—would be required. Future FDA food additive, color additive, and GRAS substance listings would specify any approved meat or poultry product uses, and any conditions of such uses, in accord with FSIS recommendations, to the extent those recommendations are consistent with the act.

Substances whose use is GRAS, however, are exempt from the premarket approval requirements of the act and need not be listed in FDA's regulations in 21 CFR. For a substance that is not affirmed by FDA as GRAS or otherwise listed in part 182 or 184 (21 CFR part 182 or 184) of FDA's regulations, or for a GRAS substance listed by FDA for general food use, where meat or poultry uses are neither specified nor prohibited, FSIS would continue to

consider a manufacturer's basis for claiming GRAS status and suitability for use in meat or poultry products. In such cases, FSIS would make the determination in consultation with FDA as needed to ensure that appropriate advice is given and that FDA has notice of the determination.

This proposal would require, and lead to, greater harmonization, i.e., closer and more consistent cooperation, between FDA and FSIS. The agencies propose to enter into a memorandum of understanding (MOU) concerning the specifics of the agencies' working relationship under the proposed regulations. A draft of the MOU is appended to the FSIS proposal appearing elsewhere in this issue of the Federal Register.

FSIS and FDA believe that the public will be better served by having all permitted uses for food additives, color additives, and GRAS substances consolidated in one place—in Title 21 CFR—and intend to work toward that end. However, existing regulations on specific substances and substance uses in Titles 9 and 21 CFR would not be immediately affected by this proposal. Because of resource constraints, current FDA regulations would be amended to accommodate meat and poultry uses only in response to a food additive, color additive, or GRAS petition. FSIS will review its listings accordingly and eliminate those that are redundant with FDA's Title 21 listings.

This proposed rule would amend FDA regulations to provide for: (1) Specifying any meat, meat food product, or poultry product uses of substances approved by FDA for food use and listed in 21 CFR; and (2) petitioning FDA for listing in 21 CFR of substances intended to be used in meat, meat food products, or poultry products. FDA's regulations would be amended so that all petitions to permit new substances, new uses, or new use levels of substances in meat, meat food products, or poultry products would be filed only with FDA. FDA's regulations governing color additive petitions, petitions to affirm substances as GRAS, and food additive petitions in parts 71, 170, and 171 (21 CFR parts 71, 170, and 171), respectively, would be revised to provide for joint review by FSIS of petitions filed with FDA that propose use of the substance in meat or poultry products. (In the agencies' view, it is the petitioner's burden to identify the intended meat and poultry uses of a substance.)

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule to amend 21 CFR parts 71, 170, and 171 under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires analysis of options for regulatory relief for small entities.

The principal benefit of this proposed rule is to eliminate duplicative Federal effort. Under the proposed amendments and amendments FSIS is concurrently proposing to its regulations published elsewhere in this issue of the Federal Register, separate petitions to FSIS for use of substances in meat or poultry products would no longer be required. Obtaining approval for the use in meat and poultry products of new substances or for new uses of previously approved substances would be simpler, faster, and less costly for both industry and the Federal Government than under the current system.

With this proposed rule, those substances *not* authorized for meat and poultry use under existing FDA regulations would require only one petition for rulemaking—to FDA. (For a substance that is not affirmed as GRAS by FDA or otherwise listed in 21 CFR part 182 or 184, or a substance listed by FDA for general food use, FSIS would continue to consider the manufacturer's basis for claiming GRAS status of the substance and its suitability for a specified use in meat or poultry products.) Furthermore, all users of the Federal regulations concerning the addition of substances to foods should benefit by having fewer, clearer regulations. Thus, there would be a reduction in the duplication of effort and attendant costs for all concerned.

Therefore, FDA finds that this proposed rule would not have a significant adverse economic impact. In addition, FDA certifies that there is not a significant impact on a substantial number of small entities.

Nevertheless, this proposed rule has been deemed by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget to be a significant regulatory action as defined by section 3(f)(4) of Executive Order 12866 because it raises novel legal and/or policy issues arising out of the President's priorities, namely the reinvention of government and regulatory reform initiatives. Therefore, this proposed rule has been formally reviewed by OIRA in accordance with the provisions of Executive Order 12866.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Information collection requirements have been approved by OMB for color additive petitions, petitions to affirm substances as GRAS, and food additive petitions under OMB Nos. 0910–0185, 0910–0132, and 0910–0016, respectively. FDA has determined that the proposed rulemaking would entail no new information collection from the regulated industry or other private entities. Persons seeking Federal Government approval of substances for use in meat or poultry foods would not have to submit any information not currently required for approval. However, such persons would only have to submit petitions to FDA, rather than to both FDA and FSIS, as they do now. Thus, a current, duplicative information collection requirement would be eliminated.

FDA requests comments regarding its tentative conclusions on the paperwork burden.

VI. Comments

Interested persons may, on or before March 14, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 71

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs, Reporting and recordkeeping requirements.

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.*).

* * * * *

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.