in § 172.841 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

On June 1, 1998, the President directed all Federal agencies to use ''plain language'' in all new documents. In compliance with this directive, FDA has drafted its amendment to § 172.841 using the principles of ''plain language'' set forth by the President. In amending the regulation, the agency is also making an editorial change by alphabetizing the list of regulated uses of polydextrose.

III. Environmental Impact

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. The agency received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this rule. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by November 29, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Reference

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated December 2, 1992, from the Division of Product Manufacture and Use to the Division of Petition Control, ''FAP 2A4332: Pfizer, Inc., Polydextrose in Tablespreads, Technologically Self-limiting Level, Submission of 11–12–92.''

2. Memorandum dated September 30, 1992, from the Division of Product Manufacture and Use to the Division of Petition Control, ''FAP 2A4332 (MATS #658): Pfizer, Inc., Polydextrose as a Bulking Agent/Texturizer in Tablespreads, Submission of 6–22–92.''

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

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

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.841 is amended by revising paragraph (c) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(c) Polydextrose is used in accordance with current good manufacturing practice as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use:

(1) Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies; cakes; cookies; and similar baked products);

(2) Chewing gum;

(3) Confections and frostings; dressings for salads;

(4) Film coatings on single and multiple vitamin and mineral supplement tablets;

(5) Frozen dairy desserts and mixes;

(6) Fruit spreads;

(7) Gelatins, puddings and fillings;

(8) Hard and soft candy;

(9) Peanut spread;

(10) Sweet sauces, toppings, and syrups; and

(11) Tablespreads.

* * * * *

Dated: October 20, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–27734 Filed 10–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 99F–673]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ionizing radiation to control microbial pathogens in seeds for sprouting. This action is in response to a petition filed by Caudill Seed Co., Inc.

DATES: This regulation is effective October 30, 2000. Submit written objections and requests for a hearing by November 29, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3032.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of August 16, 1999 (64 FR 44530), FDA announced that a food additive petition (FAP 9M4673) had been filed by Caudill Seed Co., Inc., 1402 West Main St., Louisville, KY 40203. The petitioner proposed that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of sources of ionizing radiation to control microbial pathogens in alfalfa and other sprouting seeds.

II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction in the number of microbial pathogens in or on seeds for sprouting.

The petitioner submitted published articles and other study reports containing data and information related to seeds for sprouting and other kinds of food in the areas of radiation chemistry, nutrition, toxicology, and microbiology. FDA has fully considered the data and studies submitted in the petition as well as other information in its files relevant to the safety and nutritional adequacy of seeds treated with ionizing radiation prior to sprouting.

The effects of ionizing radiation on the characteristics of treated foods are a direct result of the chemical reactions induced by the absorbed radiation. Scientists have compiled a large body of data regarding the effects of ionizing radiation on different foods under various conditions of irradiation. Research has established that the types and amounts of products generated by radiation-induced chemical reactions (''radiolysis products'') depend on the chemical constituents of the food and on the conditions of irradiation. Furthermore, the principles of radiation chemistry govern the extent of changes, if any, both in the nutrient levels and in the microbial load of irradiated foods. Key factors include the specific nutrient or microorganism of interest, the food, and the conditions of irradiation. See the agency's final rule permitting the irradiation of meat for FDA's discussion of radiation chemistry, nutrition, toxicology, and microbiology related to irradiation of foods under various conditions of use (62 FR 64107, December 3, 1997).

FDA has reviewed the relevant data and information submitted in the petition regarding radiation chemistry as it applies to seeds for sprouting, as well as data readily available and in the agency's files. FDA has concluded that the concentrations and types of radiolysis products formed by the irradiation of seeds for sprouting will be comparable to those products produced by the irradiation of foods of similar composition (Ref. 1). Most of these radiolysis products are formed in very small amounts and are either the same as, or structurally similar to, compounds found in foods that have not been irradiated. Thus, the chemical composition of sprouts grown from irradiated seeds will not differ in any significant manner from sprouts grown from seeds that have not been irradiated.

This petition contained no toxicity studies on the sprouts grown from irradiated seeds. Nonetheless, a review of the agency's data base and submitted published references of toxicological studies related to irradiated foods, combined with the fact that only negligible amounts of radiolysis products are expected to be present in the sprouts that are grown from irradiated seeds for sprouting, show that the estimated exposure of an individual to these radiolytic products will be negligible. Therefore, FDA has determined that no toxicity concerns are raised from the petitioned use of irradiation on seeds for sprouting (Ref. 2).

The purported technical effect of irradiating seeds for sprouting is to control the level of microbial pathogens. FDA evaluated data on the relation between various doses of radiation and the reduction of detectable levels of coliforms generally, and *Escherichia coli* 0157:H7 and *Salmonella* serotype Stanley specifically. The petitioner found that, depending on the pathogen and other factors, between 3 and 5 KiloGray (kGy) of irradiation would reduce the amount of pathogens to below detectable levels (Ref. 3). To accommodate the uncertainty of irradiation treatment and dose variation due to absorption by the target, the petitioner requested a maximum irradiation dose of 8 kGy. The agency has determined that irradiation of seeds for sprouting at levels up to 8 kGy will have the desired effect of controlling the levels of microbial pathogens on seeds for sprouting (Ref. 3).

Regarding the nutritional aspects of irradiating seeds for sprouting, it is well documented that protein, fat, and minerals are not significantly altered by irradiation within the given dose range requested in this petition (Ref. 2). The petitioner evaluated the potential loss of vitamins from irradiation of seeds for sprouting. Although there was a great deal of variability in vitamin levels of the seeds tested (*e.g.,* in studies submitted by the petitioner, vitamin A content of sprouts grown from control seeds was actually lower than that for sprouts grown from irradiated seeds), researchers did not observe any significant losses of any of the vitamins in the resultant sprouts (up to 6 kGy) when compared to nonirradiated controls. Any loss of vitamins, even if it occurs, is expected to be inconsequential when compared to total dietary nutrient consumption (Ref. 2). FDA therefore concludes, based on all the evidence before it, that irradiation of seeds for sprouting under the conditions set forth in the regulation below will not have an adverse impact on the nutritional adequacy of a person's diet.

III. Labeling

FDA has also considered whether irradiated seeds for sprouting and sprouts grown from such seeds must bear special labeling. In particular, FDA evaluated the application of § 179.26(c) (21 CFR 179.26(c)) to these products.

A. Seeds for Sprouting

Since any permissible use of ionizing radiation on seeds for sprouting must be in conformance with § 179.26(b), the label and labeling of such seeds for sprouting must comply with the requirements in § 179.26(c).

B. Sprouts Grown From Irradiated Seeds for Sprouting

It is important to recognize that in the use of radiation that is the subject of this rule, the irradiated article is not what is generally eaten because the unsprouted seeds are not normally consumed. While irradiation of the seeds for sprouting may cause some changes in the seed (for example, reduced viability of sprouting), the nutritional and flavor characteristics of the sprouts will derive from the fact that they were grown and not from the fact that the seeds were processed by irradiation. Moreover, the agency has no reason to believe that sprouts grown from irradiated seeds will differ in their sensory characteristics from sprouts grown from seeds that have not been irradiated. Therefore, the agency concludes that sprouts grown

from seeds that have been irradiated need not be labeled as treated by irradiation where the sprouts themselves have not been irradiated.

Based on the data and studies submitted in the petition and other information in the agency's files, FDA concludes that: (1) The proposed use of irradiation on seeds for sprouting at levels not to exceed 8 kGy is safe, (2) the irradiation will achieve its intended technical effect, and therefore, (3) the regulations in § 179.26 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(j) 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.

V. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by November 29, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Memorandum, K. Morehouse to J. Ziyad, February 23, 2000.

2. FDA Memorandum, I. Chen to J. Ziyad, February 28, 2000.

3. FDA Memorandum, M. Walderhaug to J. Ziyad, December 15, 1999.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.26 is amended in the table in paragraph (b) by adding entry ''10.'' under the headings ''Use'' and ''Limitations'' to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * * * * * *	
10. For control of microbial pathogens on seeds for sprouting.	Not to exceed 8.0 kGy.

* * * * *

Dated: October 20, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–27735 Filed 10–27–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 99N–1852]

Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the requirements for annual postmarketing status reports for approved human drug and biological products, and is requiring applicants to submit annual status reports for certain postmarketing studies of licensed biological products. This rule describes the types of postmarketing studies covered by these status reports, the information to be included in the reports, and the type of information that FDA would consider appropriate for public disclosure. This action will implement the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective February 27, 2001.