DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–2001–F–0049 (Formerly Docket No. 01F–0047)]

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'' or ''we'') is amending the food additive regulations to provide for the safe use of ionizing radiation for control of food-borne pathogens in crustaceans at a maximum absorbed dose of 6.0 kiloGray (kGy). This action is in response to a petition filed by the National Fisheries Institute.

DATES: This rule is effective April 14, 2014. See section VII of this document for information on the filing of objections. Submit either electronic or written objections and requests for a hearing by May 14, 2014.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA–2001–F–0049, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2001–F–0049 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Teresa A. Croce, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1281.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of February 6, 2001 (66 FR 9086), we announced that a food additive petition (FAP 1M4727) had been filed by the National Fisheries Institute, 1901 North Fort Myer Dr., Arlington, VA 22209 (petitioner). The petition 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 approved sources of ionizing radiation for control of food-borne pathogens in raw, frozen, cooked, partially cooked, shelled, or dried [1] crustaceans or cooked or ready-to-cook crustaceans processed with batter, breading, spices, or small amounts of other food ingredients. In a letter dated July 16, 2009, the petitioner asked FDA to modify the scope of the petition to exclude consideration of breaded and battered crustaceans. Subsequently, we published an amended notice of filing for the petition of February 6, 2001, in the **Federal Register** (74 FR 47592; September 16, 2009), indicating that the petition proposed to amend the regulations in part 179 to provide for the use of ionizing radiation for the control of food-borne pathogens in raw, frozen, cooked, partially cooked, shelled, or dried crustaceans, or cooked or ready-to-cook crustaceans processed with spices or small amounts of other food ingredients. On August 31, 2012, at our request the petitioner clarified the scope of its amended petition from 2009 by providing us with a list of the particular ''other food ingredients'' that would be added to the crustaceans prior to being irradiated (Ref. 2).

The petitioner requested a maximum absorbed dose of 6.0 kGy to achieve a 6-log reduction of *Listeria monocytogenes.*

II. Evaluation of Safety

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive.[2] While the source of radiation is not literally added to the food, the radiation is used to process or treat food, such that, analogous to other food processing technologies, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is to reduce the microbial load on and prolong the shelf life of crustaceans.

Under section 409(c)(3)(A) of the FD&C Act (21 U.S.C.348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the evidence establishes that the additive is safe for that use. Safe or safety in the context of food additives ''means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance.'' [3]

The FD&C Act does not prescribe the safety tests to be performed and not all food additives require the same amount or type of testing. The amount and type of testing required to establish the safety of an additive will vary depending on the particular additive and its intended use.

Specifically, in evaluating the safety of a source of radiation to treat food intended for human consumption, we must identify the various effects that may result from irradiating the food and assess whether any of these effects pose a public health concern. In this regard, the following three areas of possible concern need to be addressed: (1) Potential toxicity, (2) nutritional adequacy, and (3) potential microbiological risk from the treated food. Each of these areas is discussed in detail in this document. We have considered the data and studies submitted in the subject petition as well as additional data and information in our possession relevant to safety. This includes our previous evaluations of the safety of the irradiation of other foods, including the irradiation of poultry (''poultry rule'') (55 FR 18538; May 2, 1990), the irradiation of meat (''meat rule'') (62 FR 64107; December 3, 1997), the irradiation of molluscan shellfish

[1] Dried crustaceans refer to crustaceans with a water activity (a_w) of 0.85 or below (Ref. 1).

[2] The term ''food additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use) (21 U.S.C. 321(s)).

[3] 21 CFR 170.3(i).

(''molluscan shellfish rule'') (70 FR 48057; August 16, 2005), and the irradiation of fresh iceberg lettuce and fresh spinach (''fresh iceberg lettuce and fresh spinach rule'') (73 FR 49593; August 22, 2008).

A. Radiation Chemistry

''Radiation chemistry'' refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. Numerous studies regarding the chemical effects of ionizing radiation on different foods under varied conditions have led to a sound understanding of the fundamental principles of radiation chemistry.[4] The knowledge gained through these studies provided us with a knowledge base from which general conclusions about irradiated foods can be drawn by extrapolating from data on particular foods irradiated under specific conditions to similar types of foods irradiated under different, yet related, conditions. Overall, the data show that the type and amount of products generated by the radiation-induced chemical reactions (''radiolysis products'') are dependent upon the chemical constituents of the food and the specific conditions under which the food has been irradiated. The principles of radiation chemistry also govern the extent of change, if any, in the nutrient level and the microbial load of irradiated foods.

We have reviewed the pertinent data and information concerning radiation chemistry as it applies specifically to crustaceans irradiated at a maximum absorbed dose of 6.0 kGy. As described in the review memoranda, our safety review of the conditions of use generally focused on the effects of irradiation on the portion that individuals are most likely to consume, i.e., the meat or flesh of crustaceans.

1. Factors Affecting the Radiation Chemistry of Foods

Along with the chemical composition of the food, the specific conditions of irradiation are essential to assessing the radiation chemistry of a given food. The specific conditions include radiation dose, physical state of the food (e.g, solid or frozen versus liquid or non-frozen state, dried versus hydrated state), and ambient atmosphere (e.g., air, reduced oxygen, or vacuum). The radiation dose directly affects the levels of radiolysis products generated in a particular food; therefore, we can extrapolate from data obtained at higher radiation doses to draw conclusions about the amounts of radiolysis products expected to be generated at lower doses. Generally, the types of radiolysis products resulting from irradiation are similar to those products generated by alternative food processing methods, such as canning and cooking (Refs. 3 and 4).

The extent of chemical change that occurs when food is irradiated is also determined by the physical state of the food. When the food is in a frozen state, the initial radiolysis products have a greater tendency to recombine rather than diffuse throughout the food and react with other food components. Provided all conditions are the same, including dose and ambient atmosphere, the extent of chemical change that occurs in a specific food will be lower if the food is in a frozen state than a non-frozen state because the radiolysis products are less mobile in frozen conditions. Likewise, the extent of change in the dehydrated state is less than the change that occurs in the fully hydrated state.

Furthermore, the atmosphere can affect the formation of radiolytic products in a given food, thus having the potential to affect the chemical composition of the food. Irradiation in oxygenated environments facilitates the formation of additional oxidation-reduction (redox) agents as a result of the interaction between oxygen and the radiolysis products of water (e.g., hydrogen radical, hydroxide radical, and solvated electrons (a free electron in a solution)). Because all foods have components that are susceptible to redox reactions, an atmosphere with high oxygen content increases the likelihood of such occurrences and therefore, leads to the formation of a greater number and variety of radiolysis products when compared to an atmosphere with low oxygen content (Refs. 3 and 5). The final products of radiation-induced oxidation reactions in foods are similar to those produced by oxidation reactions induced by other processes (e.g., storage or heating in air).

In general, the types of radiolysis products generated by irradiation are similar to those produced by other food processing methods (Refs. 3 and 4). Radiation-induced chemical changes, if sufficiently large, however, may cause changes in the organoleptic or sensory properties of the food. Because food processors wish to avoid undesirable effects on taste, odor, color, or texture, there is an incentive to minimize the extent of these chemical changes in food. Thus, in most cases, the dosage selected will be the lowest dose required to achieve the desired effect, and the irradiation will be conducted under reduced oxygen levels and/or on food held at low temperatures or in the frozen state.[5]

2. Radiation Chemistry of the Major Components of Crustaceans

The major components of crustaceans are water, proteins, and lipids. Irradiation of water produces reactive hydroxyl and hydrogen radicals. These radicals are likely to recombine forming water, hydrogen gas, or hydrogen peroxide; however, they can react with other components of the irradiated food, in this instance, crustaceans, forming secondary radiolysis products. While the most significant effects of irradiation on the protein and lipid components of crustaceans result from chemical reactions induced by radicals generated from the radiolysis of water, additional radiolysis products can result directly from the absorbed radiation. These products form in very small amounts and are the same as or similar to compounds found in food that have not been irradiated (Ref. 4).

Because meat is high in protein, lipids, and water, the radiation chemistry of proteins, lipids, and water (in both liquid and frozen states) was extensively discussed in the preamble to the meat rule (62 FR 64107 at 64110 to 64111). The radiation chemistry of proteins and lipids discussed in the meat rule is also relevant to other flesh foods, including foods such as poultry and fish, that may be referred to as ''meat'' in common usage, but that do not conform to the definition of meat in 9 CFR 301.2.

Crustaceans are similar to other flesh foods in that they consist predominately of protein (up to 21 percent), lipid (approximately 1 to 2 percent), and water (74 to 84 percent). However, they differ from other flesh food in that they contain lower levels of fat and slightly higher levels of carbohydrate (up to 2.5 percent) by weight of the raw edible portion (Ref. 6). While the carbohydrate level in crustaceans is slightly higher than in other flesh foods, the overall level remains relatively low.

a. *Proteins.* We have previously provided a detailed discussion of

[4] Several books provide more detailed discussions of radiation chemistry with references to the large number of original research studies, particularly in the area of food irradiation. Sources that can be consulted for further information include, but are not limited to: ''Radiation Chemistry of Major Food Components,'' edited by P.S. Elias and A.J. Cohen, Elsevier, Amsterdam, 1977; ''Recent Advances in Food Irradiation,'' edited by P.S. Elias and A.J. Cohen, Elsevier, Amsterdam, 1983; and J.F. Diehl, ''Chemical Effects of Ionizing Radiation,'' Chapter 3 in ''Safety of Irradiated Foods,'' Marcel Dekker, New York, 1995.

[5] In the case of crustaceans, irradiation would occur under either chilled or frozen conditions. This temperature requirement is not necessary for dried crustaceans because they are shelf stable due to their low water activity.

protein radiation chemistry in the meat and molluscan shellfish rules. Studies conducted with high-protein foods such as meat, poultry, and seafood, have established that most of the radiolysis products derived from proteins possess the same amino acid composition and may be denatured (i.e., only altered in their secondary and tertiary structures). Although the changes to proteins caused by ionizing radiation are similar to those that occur as a result of heating, the changes are far less pronounced and the amounts of reaction products generated are far lower (Refs. 4 and 7). Studies have established that there is little change in the amino acid composition of fish irradiated at doses of 50 kGy and below, which is above the maximum absorbed dose for crustaceans—6.0 kGy (Ref. 8). Therefore, we conclude that no significant change in the amino acid composition of crustaceans is expected to result from the conditions set forth in this regulation.

b. *Carbohydrates.* The main effects of ionizing radiation on carbohydrates in foods have been studied extensively and discussed at length in the scientific literature (Refs. 9 and 10) as well as in reviews by such bodies as the World Health Organization (WHO) (Ref. 11). In the presence of water, carbohydrates react primarily with the hydroxyl radicals generated by radiolysis of water resulting in the abstraction of hydrogen from the carbon-hydrogen bonds of the carbohydrate, forming water and a carbohydrate radical. Carbohydrate radicals may result from ionization of monosaccharides such as glucose or polysaccharides such as starch. In polysaccharides, the glycosidic linkages between constituent monosaccharide units may be broken, effectively shortening the polysaccharide chains. Starch may be degraded into dextrins, maltose, and glucose. Sugar acids, ketones, and other sugar monosaccharides may also be formed as a result of ionizing radiation. Various studies have demonstrated that radiation-induced products formed from starches of different origin are qualitatively similar. The overall effects of ionizing radiation on carbohydrates are the same as those caused by cooking and other food processing treatments, and carbohydrates present as a component of food are less sensitive to the effects of irradiation than pure carbohydrates (Ref. 3). No significant change in the carbohydrate composition of crustaceans is expected to occur under the conditions set forth in this regulation, i.e., at a maximum absorbed dose of 6.0 kGy.

c. *Lipids.* We have previously provided a detailed discussion on the radiation chemistry of lipids in both the preambles to the meat and molluscan shellfish rules (62 FR 64107 at 64110 to 64111 and 70 FR 48057 at 48060, respectively). This discussion noted that studies have identified a variety of radiolysis products derived from lipids. These include fatty acids, esters, aldehydes, ketones, alkanes, alkenes, and other hydrocarbons, which are identical or analogous to compounds found in foods that have not been irradiated, but have been subjected to a different type of processing (Refs. 12 and 13). Heating food causes the lipids to produce these types of compounds, but in levels far greater than the trace amounts produced from irradiating food (Ref. 14).

One major difference between fish (both shellfish and finfish) and other flesh foods is the predominance of polyunsaturated fatty acids (PUFAs) in the lipid phase of fish. PUFAs are a subclass of lipids that have a higher degree of unsaturation in the hydrocarbon chain compared to saturated (e.g., stearic acid) or monounsaturated (e.g., oleic acid) fatty acids. The PUFA subclass of lipids is generally more susceptible to oxidation than saturated fatty acids due to their higher degree of unsaturation. Therefore, PUFAs could be more radiation-sensitive compared to the other lipid components, as suggested by some studies on irradiated oil (Ref. 15). However, evidence from studies in meat suggests that the protein component of meat may protect lipids from oxidative damage (Ref. 3).

The effects of irradiation on PUFAs in fish have been described in several studies we have reviewed, which are also discussed in detail in the molluscan shellfish rule. These studies show that irradiation is not likely to have a significant effect on the lipid composition of seafood. For example, Adams et al. studied the effects of irradiation on the concentration of PUFAs in herring and showed that irradiation of herring fillets at sterilizing doses (50 kGy), well above the petitioned maximum dose for crustaceans, had no effect on the concentration of PUFAs (Ref. 16). Armstrong et al. conducted a study to evaluate the effects of ionizing radiation on fatty acid composition in fish and concluded that no significant changes occurred in the fatty acid profiles upon irradiation at 1, 2, or 6 kGy (Ref. 17). Sant'Ana and Mancini-Filho studied the effects of irradiation on the distribution of fatty acids in fish, evaluating two monounsaturated fatty acids and seven PUFAs before and after irradiation at 3 kGy (Ref. 18). They observed insignificant changes in the concentration of total monounsaturated fatty acids and an approximately 13 percent decrease in total PUFAs at 3 kGy; these losses were largely attributed to a loss of the long chain PUFAs. Research conducted by FDA on various species of seafood also demonstrated that the concentrations of PUFAs are not significantly affected by irradiation (Refs. 19 and 20). More recently, a study conducted by Sinanoglou et al. reported non-significant changes in total fat and total fatty acids for mollusks and crustaceans with irradiation at 4.7 kGy, confirming our earlier conclusions that irradiation does not significantly affect PUFAs (Ref. 21). Therefore, based on the totality of evidence, we conclude that no significant loss of PUFAs is expected to occur in the diet under the conditions of irradiation set forth in this regulation.

3. Radiation Chemistry of Food Ingredients Added to Crustaceans

The petitioner clarified that the ''other food ingredients'' intended to be added to the crustaceans prior to treatment with irradiation included spices,[6] minerals, inorganic salts, citrates, citric acid, and calcium disodium EDTA (calcium disodium ethylene-diaminetetraacetate).[7] We considered the list of compounds and determined that for any mineral or inorganic salt, there will be no change in the exposure to radiolysis products because these compounds are not impacted by the direct or secondary effects of irradiation (Ref. 22). Furthermore, upon assessment of the organic compounds that were requested, we determined that these compounds (i.e., citric acid, citrates, and calcium disodium EDTA) will react when irradiated to form products at low levels (concentrations below the parts per billion level) that are similar to products that are formed as a result of lipid oxidation reactions, such as carbon dioxide and formic acid. As we stated in section II.2.c., we have previously evaluated the safety of the radiolysis products formed as a result of lipid

[6] The term ''spice'' refers to dried or dehydrated aromatic vegetable substances that are used in small amounts solely for flavoring or aroma (e.g., black pepper, red pepper, and bay leaves). This term is consistent with the currently regulated use of ''spice'' in § 179.26(b)(5) (21 CFR 179.26(b)(5)).

[7] This regulation addresses the irradiation of these ''other food ingredients'' to the extent that their use in crustaceans is authorized. The use of other ingredients in crustaceans prior to irradiation must be consistent with existing food additive regulations, generally recognized as safe determinations, and prior sanctions. For example, calcium disodium EDTA is approved for use under the conditions specified in 21 CFR 172.120 in cooked canned shrimp and cooked canned crabmeat and is not approved for use in other types of shrimp or crabmeat or in other crustaceans.

oxidation reactions and have concluded that these products are not harmful. Moreover, the addition of these specific organic compounds to crustaceans prior to irradiation results in the formation of these radiolysis products at such low levels that irradiation of crustaceans with the proposed additional food ingredients will not meaningfully increase exposure to radiolysis products (ibid.).

Overall, we concluded that the irradiation of all proposed ingredients will not increase the exposure to radiolysis products when used on crustaceans at levels consistent with good manufacturing practices (GMP) and in accordance with other applicable laws and regulations.

4. Consideration of Furan as a Radiolysis Product

During our review of the chemical effects of irradiation, as a part of the evaluation of this and other irradiation petitions, we became aware of a report that suggested irradiating apple juice (''apple juice report'') may produce furan (Ref. 23). Studies have demonstrated that furan can cause tumors in laboratory animals. This prompted us to initiate research on whether the apple juice report was accurate and whether furan was a common radiolysis product in food. We confirmed that certain foods form furan in low quantities when irradiated. Our studies also show that some foods form furan when heated and other foods form furan during storage at refrigeration temperatures (Ref. 24). Testing of irradiated raw shrimp and cooked crab meat show that if furan is formed when these foods are irradiated, it is formed at levels that are below the limit of detection of the available analytical methods, or below the background levels of natural furan formation during storage (Ref. 25). Therefore, because all crustaceans have similar composition, we concluded that the consumption of irradiated crustaceans will not increase the amount of furan in the diet.

5. Consideration of 2-Alkylcyclobutanones as Radiolysis Products

A class of radiolysis products derived from lipids, identified as 2-alkylcyclobutanones (2–ACBs), has been reported to form in small quantities when fats are exposed to ionizing radiation. These compounds were once considered to be unique products, formed in small quantities during the irradiation process; however, a recent report has demonstrated that 2–ACBs also can be detected in non-irradiated food (Ref. 26). The type of 2–ACBs formed depends on the fatty acid composition of the food. For example, 2-dodecylcyclobutanone (2–DCB) is a radiation by-product of triglycerides with esterified palmitic acid. Researchers have reported that 2–DCB is formed in small amounts (less than 1 microgram per gram lipid per kGy) in irradiated chicken (Ref. 27) and in even smaller amounts in irradiated ground beef (Ref. 28). Both of these foods are of relatively high total fat and palmitic acid content (Ref. 6).

In the molluscan shellfish rule, we provided a detailed discussion of the significance of the formation of 2–DCB to the safety evaluation of irradiated molluscan shellfish, a food which, like chicken, ground beef, and crustaceans, contains significant amounts of triglycerides with esterified palmitic acid (70 FR 48057 at 48065 to 48067). We concluded that no issues were raised that had not been previously considered in the meat and poultry final rules (70 FR 48057 at 48060 and 48065 to 48067). In our assessment in the meat rule, we considered all of the available data and information, including the results of genotoxicity studies and previously reviewed studies in which animals were fed diets containing irradiated meat, poultry, and fish (62 FR 64107 at 64113). While 2–DCB and other alkylcyclobutanones would be expected to be present in these irradiated foods, we found no evidence of toxicity attributable to the consumption of these substances. The macronutrient composition of crustaceans (protein, lipid, carbohydrate) is comparable to other flesh foods (Ref. 6). Due to the similar lipid levels, the formation of 2–ACBs in crustaceans is expected to be similar to the levels of 2–ACBs produced in other flesh foods. Therefore, considering all available data and information, the formation of 2–ACBs from irradiating crustaceans under the conditions proposed in this petition is not a safety concern.

B. Toxicological Considerations

To adequately evaluate the safety of irradiated food products, we assessed all available toxicological data from the relevant toxicology studies of which we are aware. For the toxicological evaluation of irradiated crustaceans, the relevant studies are those studies examining flesh-based foods, including studies on fish high in PUFAs. These include 24 long-term feeding studies, 10 reproduction/teratology studies, and 15 genotoxicity studies with flesh-based foods irradiated at doses from 6 to 74 kGy. No toxicologically significant adverse effects attributable to irradiated flesh foods were observed in any of the studies, all of which were discussed in detail in the meat rule (62 FR 64107 at 64112 to 64114). The dose of irradiation used in the relevant studies was similar to, or considerably higher than, the maximum absorbed dose requested in this petition (6.0 kGy). Therefore, these data demonstrate that crustaceans irradiated at levels up to 6.0 kGy will not present a toxicological hazard (Ref. 7).

In evaluating the safety of irradiated crustaceans, we also relied upon the integrated toxicological database derived from the extensive body of work reviewed by us (Ref. 29) and by WHO relevant to the assessment of the potential toxicity of irradiated foods. Although these studies are not all of equal quality or rigor,[8] we concluded that the quantity and breadth of testing, as well as the number and significance of endpoints assessed would have identified any real or meaningful hazard. The overwhelming majority of studies showed no evidence of toxicity. In those few instances where adverse effects were reported, we found that those effects have not been consistently reproduced in related studies conducted at higher doses or for longer durations, as would be expected if the effects were attributable to irradiation (62 FR 64107 at 64112 to 64114).

Similarly, during the early 1980s, a joint Food and Agriculture Organization/International Atomic Energy Agency, World Health Organization (FAO/IAEA/WHO) Expert Committee evaluated the toxicological and microbiological safety and nutritional adequacy of irradiated foods. The Expert Committee concluded that irradiation of any food commodity at an average dose of up to 10 kGy presents no toxicological hazard (Ref. 30). In the 1990s, at the request of one of its member states, FAO/IAEA/WHO conducted a new review and analysis of the safety of data on irradiated foods. This more recent review included all studies in our files that we considered as reasonably complete, as well as those studies that appeared to be acceptable but had deficiencies interfering with the interpretation of the data (62 FR 64107 at 64112). The FAO/IAEA/WHO review also included data from the U.S.

[8] For example, the number of animals used in many of the early studies is smaller than that commonly used today. Complete histopathology was not always done or reported. For some studies, the data are available in only brief summary form. While many of these studies cannot individually establish safety for the previously cited reasons, they still provide important information that, evaluated collectively, supports a conclusion that there is no reason to believe that the irradiation of flesh foods presents a toxicological hazard.

Department of Agriculture (USDA) and from the German Federal Research Centre for Nutrition at Karlsruhe, Germany. FAO/IAEA/WHO concluded that the integrated toxicological database is sufficiently sensitive to evaluate safety and that no adverse toxicological effects due to irradiation were observed in the dose ranges tested (Ref. 31).

Therefore, based on the totality of evidence, we conclude that irradiation of crustaceans under the conditions proposed in this petition does not present a toxicological hazard.

C. Nutritional Considerations

It has been well established that the nutritional value of the macronutrients (proteins, fats, and carbohydrates) in the diet are not significantly altered by irradiation at the petitioned doses (Refs. 32 to 34). PUFAs, particularly long-chain, omega-3 fatty acids, are generally considered to be nutritionally important components of seafood. As noted in section II.A.2.c., PUFA levels were not reduced significantly by ionizing radiation. Thus, we conclude that, as with molluscan shellfish (70 FR 48057 at 48060), potential losses of PUFAs from irradiation of crustaceans would be expected to be minimal and have no nutritional significance.

We have carefully reviewed the data and information submitted in the petition, as well as additional information available in the scientific literature, to determine the potential impact of irradiation at a maximum absorbed dose of 6.0 kGy on the nutritional value of crustaceans (Ref. 32). In this review, FDA considered all nutrients known to be present in crustaceans, but focused primarily on those vitamins having an established sensitivity to radiation and those vitamins for which at least one of these foods [9] may be identified, under our labeling regulations, as either a ''good source'' or an ''excellent source,'' [10] for contributing more than a trivial amount to the total dietary intake of that vitamin (i.e., more than 1 to 2 percent).[11]

Irradiation of any food, regardless of the dose, has no effect on the levels of minerals that are present in trace amounts (Ref. 3). Levels of certain vitamins, on the other hand, may be reduced as a result of irradiation. The extent to which a reduction in the level of a specific vitamin occurs as a result of food irradiation depends on the specific vitamin, the type of food, and the conditions of irradiation. Not all vitamin loss is nutritionally significant; however, and the extent to which a reduction in a specific vitamin level is significant depends on the relative contribution of the food in question to the total dietary intake of the vitamin.

Crustaceans, as a group, show some variation in vitamin content, but all crustaceans are excellent sources of vitamin B_{12}, and certain crustaceans may be identified as good sources of folate, niacin, riboflavin, pyridoxine, pantothenic acid, and vitamin C. Certain crustaceans (i.e., shrimp and blue crab) contain vitamin E at levels greater than 10 percent of the current Reference Daily Allowance per reference amount customarily consumed (RACC). Of these vitamins present in crustaceans, only vitamin C, thiamin, vitamin E, and, to a lesser extent pyridoxine, are considered to be sensitive to irradiation (Ref. 32). Although thiamin is present in other types of flesh food, crustaceans are not considered a good source of thiamin (ibid.). Despite the presence of vitamin C, pyridoxine, and vitamin E in crustaceans, they make up a negligible amount of the dietary intake of these vitamins in the United States. Based on data from the USDA Continuing Survey of Food Intakes of Individuals (Ref. 35), the entire food category of ''fish/shellfish (excluding canned tuna)'' contributes to less than 1 percent of the vitamin C intake of the U.S. diet and less than 2 percent of the vitamin E and pyridoxine intakes of the U.S. diet. Furthermore, because crustaceans account for only 40 percent of the entire category of ''fish/shellfish (excluding canned tuna),'' the impact of these vitamin levels from consuming crustaceans will be of even less significance (Ref. 32). Potential losses of vitamin C, thiamine, vitamin E, and pyridoxine, as a result of irradiation of crustaceans at a maximum absorbed dose of 6.0 kGy, are of minimal to no consequence to the overall U.S. diet.

Other vitamins present in crustaceans (i.e., niacin, pantothenic acid, vitamin B_{12}, and folate) are relatively insensitive to irradiation, particularly at the doses requested by this petition. Of these vitamins, only vitamin B_{12} is provided in meaningful amounts to the U.S. diet from the intake of crustaceans. The stability of vitamin B_{12} to irradiation has been demonstrated in numerous studies and was previously discussed in the molluscan shellfish rule (70 FR 48057 at 48062). Molluscan shellfish contain the highest amounts of vitamin B_{12} among foods considered to be fish/shellfish; therefore, our evaluation and discussion in the molluscan shellfish rule are relevant to this petition. Further, in its review of this petition, we considered potential B_{12} losses in crustaceans in addition to other irradiated foods containing vitamin B_{12} (ibid.). We conclude that any potential losses of radiation-insensitive vitamins in foods, irradiated under the conditions described in this petition, would be minor and the resulting impact on nutrient intake in the U.S. diet would be negligible (ibid.).

We also analyzed the contribution of crustaceans to vitamin D intake and found that only 0.30 percent of dietary vitamin D for U.S. adults (18 years and older) comes from the consumption of crustaceans (Ref. 37). Due to this small contribution of vitamin D from crustaceans to the overall U.S. dietary intake, the potential losses of this vitamin from crustaceans irradiated under the conditions described in this regulation would be minor and the resulting health impact would be negligible.

Based on review of the available data and information, we conclude that irradiation of crustaceans with a maximum absorbed dose of 6.0 kGy will not adversely impact the nutritional adequacy of the diet.

D. Microbiological Considerations

Irradiation at the requested doses will reduce, but not entirely eliminate, the number of viable pathogenic (illness causing) microorganisms in or on crustaceans. Furthermore, as discussed in this document, irradiation of crustaceans is expected to extend the shelf-life of the treated product by reducing the number of non-pathogenic food spoilage microorganisms.

The predominant non-pathogenic bacterial flora of freshly caught fish or shellfish are from the *Pseudomonas* group, with *Acinetobacter* and *Moraxella,* generally present. As crustaceans begin to spoil, the bacteria from the *Pseudomonas* group can increase to as much as 90 percent of the

[9] Nutrient content data was available from the USDA Nutrient Database (NDB) for Standard Reference, version 23 (SR–23) for the following crustaceans: Crab (blue, king, queen, Dungeness), shrimp, lobster, and crayfish (see Refs. 6, 32, and 35).

[10] To be considered a ''good source'' a given vitamin, that particular food must contain 10–19 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) for that vitamin per reference amount customarily consumed (RACC) (21 CFR 101.54(c)). A food containing ≥ 20 percent of the RDI or DRV per RACC may be labeled as an ''excellent source'' of that vitamin (21 CFR 101.54(b)).

[11] This information is based upon individual food intake data available from nationwide surveys conducted by USDA and maintained in the USDA NDB SR–23. USDA's surveys were designed to monitor the types and amounts of foods eaten by Americans and food consumption patterns in the U.S. population. FDA routinely uses these data to estimate exposure to various foods, food ingredients, and food contaminants (see Refs. 6, 35, and 36).

total flora (Ref. 38). *Escherichia coli, Vibrio* spp., *Listeria* spp., *Salmonella* serovars, *Staphylococcus aureus,* and *Clostridium botulinum* were identified by the petitioner as the human pathogens of public health concern that are most likely to be present in or on crustaceans. The level and route of entry of the different types of microorganisms in crustaceans is variable, and this contamination can result from harvesting, handling, and transportation (Ref. 39). Vibrios are naturally present in marine environments, and consequently, present in or on crustaceans. The petitioner provided data on the potential levels of microbial pathogens in various crustacean seafoods. While most observed levels of microbial pathogens are much lower, the petitioner states that *Listeria* could be present at up to 10^4 colony forming units per gram (CFU/g), vibrios at 10^6 CFU/g, salmonellas, streptococci, and staphylococci at <10 CFU/g, and *C. botulinum* at no more than 0.17 CFU/g. Yeasts and molds also may be present; however, these organisms would be limited by aerobic packaging (i.e., oxygen-permeable packaging) and the presence of normal spoilage bacteria (Ref. 40).

The petitioner provided reports and published articles describing the effects of irradiation on the microorganisms in or on crustaceans as well as in or on other seafood. The effectiveness of irradiation is a function of the sensitivity of the target microorganisms to ionizing radiation at a dose that will retain the organoleptic and nutritional characteristics of the food. The type and physical state of the food product, its temperature, ambient atmosphere, and the survival of non-pathogens also are factors that can either enhance or diminish the survivability of the organisms treated with ionizing radiation. Data show that the more complex the milieu, the greater the level of radiation necessary to reduce the level of microorganisms (Ref. 41). Reports and published articles provide data on the doses needed to control several microorganisms of relevance, including various *Salmonella, Vibrio* spp., *S. aureus, L. monocytogenes,* and *E. coli.* Due to organoleptic considerations, the doses used will vary depending on the type of crustacean; for example, absorbed doses greater than 0.7 kGy may affect the texture of non-frozen lobster meat, whereas other types of crustaceans tolerate higher doses without experiencing undesirable changes.

There is a large body of work regarding the radiation sensitivities of non-pathogenic food spoilage microorganisms and pathogenic food-borne microorganisms. Generally, the common spoilage organisms such as *Pseudomonas* and the pathogens of concern are quite sensitive to the effects of ionizing radiation. Chen et al. investigated the microbial quality of irradiated crab meat products, including white lump meat, claw, and crab fingers (Ref. 42). The D_{10} values [12] for spoilage bacteria ranged from less than 0.40 to 0.46 kGy. Further, it was determined that the shelf-life of food products derived from the claw and finger of crabs were extended approximately 3 days beyond the unirradiated samples (ibid.). Following irradiation fresh, peeled, and deveined tropical shrimps stored at 10–12 degrees Celsius were found to have an increase in shelf-life to 10–14 days when irradiated at 1.5 kGy and 18–21 days when irradiated at 2.5 kGy as compared to the unirradiated control samples, which spoiled within 4 days (Ref. 43). In a study performed by Scholz et al., irradiation at 5 kGy extended the shelf-life of Pacific shrimp (*Pandalus jordani*) to 5 weeks when stored at 3 degrees Celsius (Ref. 44).

Information regarding doses needed for control of pathogenic organisms in the petition and other information in our files show that D_{10} values for vibrios can range from less than 0.10 up to 0.75 kGy depending on the crustacean, its physical state, temperature, and other factors (Refs. 39, 42, 45, and 46). In frozen, unpeeled, and uncooked shrimp, the D_{10} values for *L. monocytogenes* ranged from 0.7 kGy to 0.88 kGy (Refs. 39 and 47) and in crab meat, the D_{10} value cited in the literature was 0.59 kGy (Ref. 42).[13] The D_{10} values cited in the published literature for several *Salmonella* serotypes in grass prawns and shrimp homogenate ranged from 0.30 to 0.59 kGy (Refs. 45, 49, and 50). Thus, irradiation of crustaceans at a maximum absorbed dose of 6.0 kGy would be effective at controlling pertinent pathogens (Ref. 40).

In evaluating the subject petition, we have carefully considered whether irradiation of crustaceans under the conditions proposed in the petition could result in significantly altered microbial growth patterns such that these foods would present a greater microbiological hazard than comparable food that had not been irradiated. In considering this issue, we focused on whether the proposed irradiation conditions would increase the probability of significantly increased growth of, and subsequent toxin production by, *C. botulinum* because this organism is relatively resistant to radiation in comparison to non-spore forming bacteria. We have concluded that the possibility of increased microbiological risk from *C. botulinum* is extremely remote because: (1) The conditions of refrigerated storage necessary to maintain the quality of crustaceans are not amenable to the outgrowth and production of toxin by *C. botulinum* and (2) sufficient numbers of spoilage organisms will survive such that spoilage will occur before outgrowth and toxin production by *C. botulinum* (Refs. 40 and 51).

Based on the available data and information, we conclude that irradiation of crustaceans conducted in accordance with current GMP under 21 CFR 172.5 will reduce bacterial populations without increased microbial risk from pathogens that may survive the irradiation process.

III. Comments

We have received numerous comments, primarily form letters, from individuals stating their opinions regarding the potential dangers and unacceptability of irradiating food. We have also received several comments from individuals or organizations stating their opinions regarding the potential benefits of irradiating food and urging us to approve the petition. None of these letters contain any substantive information relevant to a safety evaluation of irradiated crustaceans. Additionally, we received several comments from Public Citizen (PC) and the Center for Food Safety (CFS) requesting the denial of this and other food irradiation petitions, as well as joint comments from CFS and Food and Water Watch (FWW).

Overall, the comments were of a general nature and not specific to the requests in the individual petitions. These comments raised a number of topics, including studies reviewed in the 1999 FAO/IAEA/WHO report on high-dose irradiation; a review article that analyzed studies of irradiated foods performed in the 1950s and 1960s; the findings of a 1971 study in which rats were fed irradiated strawberries; the findings regarding reproductive performance in a 1954 study in which mice were fed a special irradiated diet; issues regarding mutagenicity studies; certain international opinions; issues

[12] D_{10} is the absorbed dose of radiation required to reduce a bacterial population by 90 percent.

[13] The petitioner requested a maximum absorbed dose of 6.0 kGy to achieve a 6-log reduction of *L. monocytogenes.* Dividing the treatment dose by the appropriate D_{10} value estimates the log reduction for a given treatment dose (e.g., 6 kGy divided by 0.88 for frozen, unpeeled, uncooked shrimp has the potential to yield a 6.8 log reduction) (Ref. 48). This demonstrates that it is possible to achieve a 6-log reduction of *L. monocytogenes* with a maximum absorbed dose of 6 kGy.

related to ACBs, including purported promotion of colon cancer; the findings of certain studies conducted by the Indian Institute of Nutrition in the 1970s; general issues regarding toxicity data; our purported failure to meet statutory requirements; data from a 2002 study purportedly showing an irradiation-induced increase in trans fatty acids in ground beef; studies regarding purported elevated hemoglobin levels and their significance; and an affidavit describing the opinions of a scientist regarding the dangers of irradiation and advocating the use of alternative methods for reducing the risk of food-borne disease. The topics raised in the FWW/CFS comments included issues with ACBs, our purported failure to define a list of foods covered by the petition; general issues with toxicity data; purported microbiological resistance; and purported negative effects on organoleptic properties.

Many of the comments from PC and CFS were also submitted to the dockets for the rulemakings on the irradiation of molluscan shellfish (Docket No. 1999F–4372, FAP 9M4682) and on the irradiation of fresh iceberg lettuce and fresh spinach (Docket No. FDA–1999–F–2405, FAP 9M4697). For a detailed discussion of our responses to the previously mentioned general comments, we refer to the molluscan shellfish rule (70 FR 48057 at 48062 to 48071). For a detailed discussion of our response to the FWW/CFS comments, we refer to our fresh iceberg lettuce and fresh spinach rule (73 FR 49593 at 49600–49601).

Accordingly, because these comments do not raise issues specific to irradiated crustaceans and because we have already responded to these comments elsewhere, we are not further addressing these comments in this document.

There were no additional comments submitted to this docket.

IV. Conclusions

Based on the data and studies submitted in the petition and other information in our files, we conclude that the proposed use of irradiation to treat chilled or frozen raw, cooked, or partially cooked crustaceans, or dried crustaceans, with or without spices, minerals, inorganic salts, citrates, citric acid, and/or calcium disodium EDTA used in accordance with applicable laws and regulations, is safe, providing that the absorbed dose does not exceed 6.0 kGy. Therefore, we are amending § 179.26 as set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition are available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

V. Environmental Impact

We have previously considered the environmental effects of this rule as announced in the notice of filing for FAP 1M4727 (66 FR 9086). No new information or comments have been received that would affect our previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. 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.

VII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

VIII. Section 301(*ll*) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(*ll*) of the FD&C Act (21 U.S.C. 331(*ll*)). Section 301(*ll*) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exceptions in section 301(*ll*)(1) to (4) of the FD&C Act applies. In its review of this petition, FDA did not consider whether section 301(*ll*) of the FD&C Act or any of its exemptions apply to irradiated crustaceans. Accordingly, this final rule should not be construed to be a statement that irradiated crustaceans, if introduced or delivered for introduction into interstate commerce, would not violate section 301(*ll*) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore, should not be construed to be a statement of the likelihood that section 301(*ll*) of the FD&C Act applies.

IX. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. References without asterisks are not on display; they are available as published articles and books.

1. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, ''Fish and Fishery Products Hazards and Control Guidance,'' 4th Ed., November 2011, Chapters 12 and 14, available at *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm2018426.htm.*

*2. L. Weddig, National Fisheries Institute, email message to T. Croce, FDA, August 31, 2012.

3. Diehl, J. F., ''Chemical Effects of Ionizing Radiation,'' in *Safety of Irradiated Foods,* 2nd Ed., Marcel Dekker, Inc., New York, pp. 43–88, 1995.

*4. Memorandum for FAP 1M4727 from D. Folmer, FDA, to L. Highbarger, FDA, August 2, 2002.
5. Diehl, J. F., ''Radiolytic Effects in Foods,'' in *Preservation of Foods By Ionizing Radiation,* vol. 1, E.S. Josephson and M.S. Peterson, eds., CRC Press, Boca Raton, FL, pp. 279–357, 1982.
6. U.S. Department of Agriculture, Agricultural Research Service, USDA National Nutrient Database for Standard Reference, Release 23. Nutrient Data Laboratory home page, *http://www.ars.usda.gov/ba/bhnrc/ndl.*
*7. Memorandum for FAP 1M4727 from I. Chen, FDA, to L. Highbarger, FDA, April 7, 2003.
*8. Uderdal, B., J. Nordal, G. Lunde, and B. Eggum, ''The Effect of Ionizing Radiation on the Nutritional Value of Fish (Cod) Protein,'' *Lebensmittel-Wissenschaft Technologie,* 6:90–93, 1973.
9. Adam, S., ''Recent Developments in Radiation Chemistry of Carbohydrates,'' in *Recent Advances in Food Irradiation,* P.S. Elias and A.J. Cohen, eds., Elsevier Biomedical, Amsterdam, pp. 149–170, 1983.
*10. Raffi, J., J. P. Agnel, C. Thiery, et al., ''Study of Gamma Irradiated Starches Derived From Different Foodstuffs: A Way for Extrapolating Wholesomeness Data,'' *Journal of Agricultural and Food Chemistry,* 29:1227–1232, 1981.
11. WHO, ''Safety and Nutritional Adequacy of Irradiated Food,'' World Health Organization, Geneva, 1994.
*12. Kavalam, J. P. and W. W. Nawar, ''Effects of Ionizing Radiation on Some Vegetable Fats,'' *Journal of the American Oil Chemical Society,* 46:387–390, 1969.
13. Delincée, H., ''Recent Advances in Radiation Chemistry of Lipids,'' in *Recent Advances in Food Irradiation,* edited by P.S. Elias and A.J. Cohen, Elsevier, Amsterdam, pp. 89–114, 1983.
14. Nawar, W. W., ''Comparison of Chemical Consequences of Heat and Irradiation Treatment of Lipids,'' in *Recent Advances in Food Irradiation,* P. S. Elias and A. J. Cohen, eds., Elsevier Biomedical, Amsterdam, pp. 115–127, 1983.
*15. International Consultative Group on Food Irradiation (ICGFI), ''Monograph on Irradiation of Fish, Shellfish, and Frog Legs,'' Fifteenth Meeting of the ICGFI, Vienna, 1998.
*16. Adams, S., G. Paul, and D. Ehlerman, ''Influence of Ionizing Radiation on the Fatty Acid Composition of Herring Fillets,'' *Radiation Physics Chemistry,* 20:289–295, 1982.
*17. Armstrong, S. G., S. G. Wyllie, and D. N. Leach, ''Effects of Preservation by Gamma-Irradiation on the Nutritional Quality of Australian Fish,'' *Food Chemistry,* 50:351–357, 1994.
*18. Sant'Ana, L. S. and J. Mancini-Filho, ''Influence of the Addition of Antioxidants in Vivo on the Fatty Acid Composition of Fish Fillets'' *Food Chemistry,* 68:175–178, 2000.
*19. Morehouse, K. M. and Y. Ku, ''Gas Chromatographic and Electron Spin Resonance Investigation of Gamma-Irradiated Shrimp,'' *Journal of Agriculture and Food Chemistry,* 40(10):1963–1971, 1992.
20. Morehouse, K. M., ''Identification of Irradiated Seafood,'' in *Detection Methods for Irradiated Foods: Current Status,* edited by C. H. McMurray, E. M. Stewart, R. Gray, and J. Pearce, The Royal Society of Chemistry, Cambridge, United Kingdom, pp. 249–258, 1996.
*21. Sinanoglou, V. J., A. Batrinou, S. Konteles, and K. Sflomos, ''Microbial Population, Physiochemical Quality, and Allergenicity of Molluscs and Shrimp Treated With Cobalt-60 Gamma Radiation,'' *Journal of Food Protection,* 70(4): 958–966, 2007.
22. Memorandum for FAP 1M4727 from K. Morehouse, FDA, to T. Croce, FDA, May 30, 2013.
23. Seibersdorf Project Report, International Programme on Irradiation of Fruit and Fruit Juices, Chemistry and Isotopes Department, National Centre for Nuclear Energy, Madrid, Spain, vol. 8, 1966.
*24. Memorandum for FAP 9M4697 from K. Morehouse, FDA, to L. Highbarger, FDA, February 20, 2008.
*25. Memorandum for FAP 1M4727 from K. Morehouse, FDA, to T. Croce, FDA, August 18, 2010.
*26. Variyar, P. S., S. Chatterjee, M. G. Sajilata, et al., ''Natural Existence of 2-Alkylcyclobutanones,'' *Journal of Agricultural and Food Chemistry,* 56:11817–11823, 2008.
*27. Crone, A. V. J., J. T. G. Hamilton, and M. H. Stevenson, ''Effect of Storage and Cooking on the Dose Response of 2-Dodecylcyclobutanone, a Potential Marker for Irradiated Chicken,'' *Journal of the Science of Food and Agriculture,* 58:249–252, 1992.
*28. Gadgil, P., K. A. Hachmeister, J. S. Smith, and D. H. Kropf, ''2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties,'' *Journal of Agriculture and Food Chemistry,* 50:5746–5750, 2002.
*29. Memorandum to the file, FAP 4M4428, D. Hattan, Acting Director, Division of Health Effects Evaluation, November 20, 1997.
30. FAO/IAEA/WHO, ''Wholesomeness of Irradiated Food: Report of a Joint FAO/IAEA/WHO Expert Committee,'' World Health Organization Technical Report Series, No. 659, WHO, Geneva, 1981.
31. FAO/IAEA/WHO ''High Dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10kGy: Report of a Joint FAO/IAEA/WHO Study Group'' World Health Organization Technical Report Series, No. 890, WHO, Geneva, pp. 9–37, 1999.
*32. Memorandum for FAP 1M4727 from A. Edwards, FDA, to T. Croce, FDA, April 4, 2011.
*33. Arvanitoyannis, I. S., A. Stratakos, and E. Mente, ''Impact of Irradiation on Fish and Seafood Shelf Life: A Comprehensive Review of Applications and Irradiation Detection,'' *Critical Reviews in Food Science and Nutrition,* 49:68–112, 2009.
34. Shamasuzzaman, K., ''Nutritional Aspects of Irradiated Shrimp: A Review,'' Atomic Energy of Canada Ltd. AECL–10090, Whiteshell Nuclear Research Establishment, Pinawa, Manitoba, pp. 1–40, 1989.
*35. Cotton, P. A., A. F. Subar, J. E. Friday, and A. Cook, ''Dietary Sources of Nutrients among U.S. Adults, 1994 to 1996,'' *Journal of the American Dietetic Association,* 104:921–930, 2004.
*36. Memorandum for FAP 9M4697 from A. Edwards, FDA, to L. Highbarger, FDA, July 16, 2008.
*37. Memorandum for FAP 9M4697 from L. Brookmire, FDA, to T. Croce, FDA, June 19, 2011.
38. Grodner, R. M. and L. S. Andrews in ''Irradiation,'' pp. 429–440, in *Microbiology of Marine Food Products,* Van Nostrand Reinhold, New York, 1991.
*39. Rashid, H. O., H. Ito, and I. Ishigaki, ''Distribution of Pathogenic Vibrios and Other Bacteria in Imported Frozen Shrimps and Their Decontamination by Gamma-Irradiation,'' *World Journal of Microbiology and. Biotechnology,* 8:494–499, 1992.
*40. Memorandum for FAP 1M4727 from R. Merker, FDA, to T. Croce, FDA, April 11, 2011.
*41. Thayer, D.W., G. Boyd, W.S. Muller, et al., ''Radiation Resistance of Salmonella,'' *Journal of Industrial Microbiology,* 5:383–390, 1990.
*42. Chen, Y. P., L. S. Andrews, and R. M. Grodner, ''Sensory and Microbial Quality of Irradiated Crab Meat Products,'' *Journal of Food Science,* 61:1239–1242, 1996.
*43. Kumta, U. S., S. S. Mavinkurve, M. S. Gore, et al., ''Radiation Pasteurization of Fresh and Blanched Tropical Shrimps,'' *Journal of Food Science,* 35:360–363, 1970.
*44. Scholz, D. J., R. O. Sinnhuber, D. M. East, and A. W. Anderson, ''Radiation-Pasteurized Shrimp and Crabmeat,'' *Food Technology,* 16:118–120, 1962.
*45. Hau, L.-B., M.-H. Liew, and L.-T. Yeh, ''Preservation of Grass Prawns by Ionizing Radiation,'' *Journal of Food Protection,* 55:198–202, 1992.
*46. Ito, H., P. Adulyatham, N. Sangthong, and I. Ishigaki, ''Effects of Gamma-Irradiation on Frozen Shrimps to Reduce Microbial Contamination,'' *Radiation and Physical Chemistry,* 34:1009–1011, 1989.
*47. Ito, H., H. O. Rashid, N. Sangthong, et al., ''Effect of Gamma Irradiation on Frozen Shrimps for Decontamination of Pathogenic Bacteria,'' *Radiation Physics and Chemistry,* 42:279–282, 1993.
48. Ley, F. J., ''The Effect of Ionizing Radiation on Bacteria,'' in *Manual on Radiation Sterilization of Medical and Biological Materials.* IAEA, Vienna, pp. 37–64, 1973.
*49. Nerkar, D. P. and J. R. Bandekar, ''Elimination of Salmonella From Frozen Shrimp by Gamma Radiation,'' *Journal of Food Safety,* 10:175–180, 1990.
50. Nouchpramool, K., S. Pungsilpa, and P. Adulyatham, ''Improvement of Bacteriological Quality of Frozen Shrimp by Gamma Radiation,'' Office of Atomic

Energy for Peace (Bangkok, Thailand). (023535000; 4868000)), ISBN 974–7399–29–6, 1985.

51. Jimes, S., ''Clostridium Botulinum Type E in Gulf Coast Shrimp and Shucked Oysters and Toxin Products as Affected by Irradiation Dosage, Temperature, Storage Time, and Mixed Spore Concentrations,'' dissertation submitted to Louisiana State University, pp. ix and 1, 1967.

List of Subjects in 21 CFR Part 179

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 item 14 to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * *	* *
14. For control of food-borne pathogens in, and extension of the shelf-life of, chilled or frozen raw, cooked, or partially cooked crustaceans or dried crustaceans (water activity less than 0.85), with or without spices, minerals, inorganic salts, citrates, citric acid, and/or calcium disodium EDTA.	Not to exceed 6.0 kGy.

* * * * *

Dated: April 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07926 Filed 4–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2013–N–0568]

Physical Medicine Devices; Reclassification of Stair-Climbing Wheelchairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify stair-climbing wheelchairs, a class III device, into class II (special controls) based on new information and subject to premarket notification, and further clarify the identification.

DATES: This order is effective April 14, 2014.

FOR FURTHER INFORMATION CONTACT: Mike Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at