



December 13, 2007

Lane A. Highbarger, Ph.D.  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition (HFS-255)  
Office of Food Additive Safety  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Expression of opposition to petition for use of ionizing radiation on dietary supplements and dietary ingredients (Docket No. 03F-0182)

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Dear Dr. Highbarger,

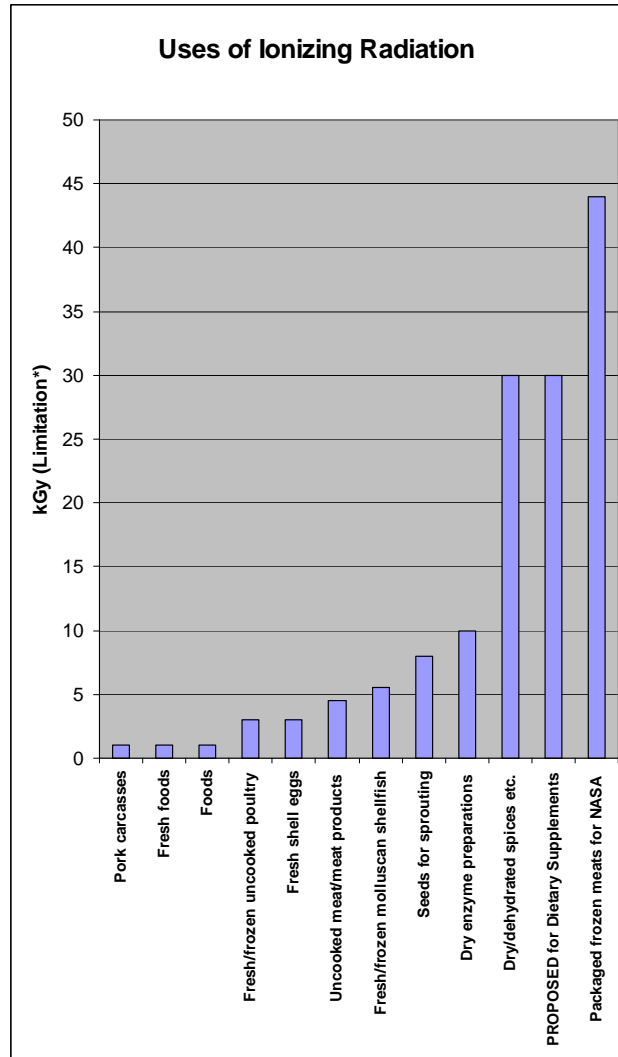
The American Herbal Products Association (AHPA) has recently become aware of a food additive petition filed by Steris Corp. to allow the use of ionizing radiation for the control of microbial contamination on dietary supplements and dietary ingredients (FAP 2M4741). A Federal Register notice on May 9, 2003 stated that this petition proposes 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 ionizing radiation for the control of microbial contamination on dietary supplements, and ingredients used in the manufacture of dietary supplements, up to a maximum absorbed dose of 30 kGy. 68 FR, 25048.

AHPA is the trade association and voice of the herbal products industry, and is comprised of domestic and foreign companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of herbal products.

AHPA and its members object to and are opposed to any approval by the Food and Drug Administration of the above-identified food additive petition, and are requesting by this letter that the petition be denied. Dietary supplement products consist of vitamins, minerals, herbs and other botanicals, amino acids, and certain other dietary substances. AHPA believes that proper handling of these ingredients under current good manufacturing practice is usually sufficient to ensure that dietary supplements are not subject to microbial contamination that presents any risk to the health of consumers of these products. Thus, there is generally no need for ionizing radiation as a treatment for this class of goods and the ingredients from which they are made.

In addition, AHPA notes that this petition proposes the use of ionizing radiation on dietary supplements “up to a maximum absorbed dose of 30 kiloGray (kGy).” AHPA further notes that FDA has previously approved the use of ionizing radiation on just

eleven food categories and has established specific limitations on the levels of irradiation allowed in each of these food categories (21 CFR 179.26). The following chart provides a graphic representation of the established limits in each of these categories and the proposed level that would be allowed under the food additive petition that is the subject of these comments.



\*Limitation is the maximum amount allowed in all but the last (NASA) use, where the limitation is stated as a minimum amount (44 kGy).

As is obvious from the above chart, Steris Corp., in proposing that the limitation of ionizing radiation for dietary supplements be established at 30 kGy, is suggesting that this limit be from 3 to 30 times higher than is currently allowed for all but two food categories: (1) For the sterilization of frozen, packaged meats used solely in the NASA space flight programs; and (2) for microbial disinfection of spices, etc. (“the following

dry or dehydrated aromatic vegetable substances ...: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances [and] turmeric and paprika... when they are to be used as color additives”), but ONLY when these are “used as ingredients in small amounts solely for flavoring or aroma.” In other words, Steris Corp. has proposed that only astronauts would be able to obtain foods treated with higher limits of ionizing radiation than dietary supplements, and has apparently ignored the fact that, while spices are used in small amounts, dietary supplements may be consumed in quantities of several grams per day. Thus, dietary supplement consumers will be exposed to much higher levels of any material changes that occur in a supplement’s or ingredient’s characteristics or in its consequences of use, if any, as a result of the irradiation. Given the wide range of ingredients found in these products, the nature and extent of such changes may vary depending on the type of supplement.

AHPA therefore herein records its concern that, even if FDA should approve this food additive petition, contrary to AHPA’s express opposition, the proposed limitation of a level of up to 30 kGy is entirely unacceptable. In addition, AHPA notes that the Federal Food, Drug and Cosmetic Act (FFDCA) requires that if “a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary (A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and (B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect” (FFDCA § 409(c)(4)). AHPA is not aware of any information that has been provided to address either of these two statutory requirements.

Furthermore, AHPA points out that the category “dietary supplements” comprises an extremely broad range of products with very different chemical and microbiological properties. Therefore, AHPA believes it is inappropriate to establish one level of treatment, or any treatment, for all dietary supplements as a group. Rather, different types of supplements must be evaluated separately with respect to (a) whether irradiation accomplishes the desired technical effect; (b) what level of irradiation is necessary to accomplish that effect; and (c) what types of material changes occur in the supplement or ingredient’s characteristics or in consequences of their use, if any, as a result of the irradiation. AHPA believes the results of these evaluations will be different for, say, a soft gelatin capsule containing fish oil and oil-soluble vitamins, compared to a tablet containing oyster shell or a chewable semisolid containing herbs and vitamins.

AHPA is also concerned, should this petition be approved, that the use of ionizing irradiation on herbal dietary ingredients will mask one of the factors that is currently relevant to the determination of ingredient quality. It is a standard industry practice to establish lot-by-lot specifications for such factors as absence of pathogens and quantitative limits on total microbial and yeast/mold levels. Herbal ingredients that are contaminated with pathogens, high microbial loads, or high yeast and mold loads are currently subject to rejection by manufacturers of high-quality herbal supplements. Proper cultivation, harvest, and/or post-harvest handling of herbal ingredients under good agricultural practice and good manufacturing practice serves to control against degradation of harvested materials' overall quality and the development of pathogenic bacteria and molds, and assists in limiting the levels of total microbial and yeast/mold levels. On the other hand, improper cultivation, harvest, and/or post-harvest handling can greatly increase microbial and yeast/mold levels and allow for the presence of pathogens, and can also cause general degradation of herbal materials. Thus, quantitative data on microbial and yeast/mold levels have both direct relevance by determining these levels, and are also indicative of overall quality. If this petition is approved any herbal ingredient that is subjected to ionizing irradiation would have greatly reduced microbial and yeast/mold levels, such that important information about overall quality would be absent, or in fact misrepresented. This is of particular concern in the case of pathogens, since even if pathogenic organisms are eliminated through irradiation, pathogenic by-products such as endotoxins or exotoxins may remain in the material.

Of additional concern to AHPA and its members is the likelihood, should this petition be approved, that the United States will become the dumping ground for poor quality herbal ingredients from around the world. Irradiation of herbal ingredients is not permitted in many countries. For example, under the rules of the European Commission, only specific categories of food that are sold in any of the twenty-seven European Union countries may be treated with irradiation. Allowable food categories are quite limited at this time and do not include the European product categories that are synonymous with dietary supplements in the U.S. Thus, herbal ingredients with high microbial or yeast/mold loads – which AHPA believes to be a measure of poor quality – cannot be treated with irradiation for the European market. It must be assumed that these poor quality ingredients, being prohibited from sale in the E.U. and other markets, would instead find their way to the United States if FDA approves Steris Corp.'s petition.

Finally, AHPA notes that, in considering whether to approve or deny a food additive petition, current law dictates that no regulation shall issue "if a fair evaluation of the data before the Secretary... shows that the proposed use of the additive would

promote deception of the consumer...” (FFDCA § 409(c)(3)(B)). AHPA believes that consumers of dietary supplements generally believe that these products, and especially herbal dietary supplements, are “natural products,” and that these same consumers do not believe that ionizing radiation is a natural process. Although AHPA does not have available information in the form of actual consumer surveys, it is very likely that consumers of irradiated dietary supplements would consider themselves to be deceived if they were to purchase dietary supplements that have been treated, or that bear ingredients that have been treated with ionizing irradiation at a level of 30 kGy.

This last stated concern is especially true in light of FDA’s recent proposal to amend the rules for labeling to disclose treatment of food products (including dietary supplements) with ionizing radiation, such that only those foods “in which the irradiation caused a material change in the characteristics of the food” would be required to disclose such treatment, and even then would be allowed to use plainly misleading terms such as “pasteurized” (72 FR 16291-16306<sup>1</sup>). Although AHPA was not able to submit timely comments to this proposed rule, AHPA agrees with the findings of the focus groups identified in this publication that irradiated foods should be labeled “honestly” (72 FR 16293). AHPA does not, however, believe that this proposed rule will, in fact, result in honest labeling of irradiated foods and is therefore opposed to this proposal.

Thank you for your prompt attention to the information provided here.

Respectfully submitted,



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<sup>1</sup> FDA. Irradiation in the Production, Processing and Handling of Food. Proposed Rule. April 4, 2007.