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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Citizen Petition

The undersigned submits this petition under 21 CFR 179.26 of the Food, Drug and Cosmetic Act to the Commissioner of Food and Drugs under 21 CFR 5.10 and 21 CFR 10.30, except that 10.30 (e) (2) (iii), regarding 180 day tentative responses to request the Commissioner of Food and Drug to amend the regulation.

Action Requested

Through a series of proceedings under section 409 of the act (21 U.S.C. 348), FDA has approved the use of ionizing radiation for various food uses (see Sec. 179.26 (21 CFR 179.26)). The agency's regulations require that the label and labeling of retail packages of foods treated with ionizing radiation include both the radura logo, which is the international symbol that indicates radiation treatment, and a disclosure statement (either "Treated with radiation" or "Treated by irradiation") in addition to information required by other regulations (Sec. 179.26(c)(1)). The regulations require that the logo be placed prominently and conspicuously in conjunction with the required statement. The regulation does not specify the prominence of the disclosure statement, either generally or relative to other information required in the label and labeling.

We request by way of this petition to allow irradiated fruits and vegetables that have been treated using x-ray technology be given another option for labeling. While they would still be required to place the radura logo prominently the label could read "Treated with X-ray".

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Statement of Grounds

Some consumers are still unaware of how irradiation of fruits and vegetables is of benefit to them. Many people associate irradiation with nuclear source material and have objection to supporting and development or promotion of radioactive source material. In the past three years the petitioner has demonstrated to thousands of consumers and industry professionals how an X-ray system works for post harvest treatment of fruits and vegetables. In almost all cases they ask why we have to label "treated with irradiation"? They view it as a warning sign demonstrating something might be unsafe about the food. When the petitioner asks what they would think if the label stated "Treated with X-Ray" the response is always that it is much more favorable. They are familiar and comfortable with X-Ray. Consumers use X-Ray at the doctor's office. Traveler's bags are sent through an X-Ray machine at the airport. The consumer more easily understands the phrase "Treated with X-Ray".

The legal basis for the request is very simple. X-Ray defines exactly what we do with our fruits and vegetables in our facility.

The petitioner would also request that we be allowed to add a statement on the box carton, in educational materials or promotional materials that states after "Treated with X-Ray" that would state, "For Environmental Pest Control". Many consumers in non-fruit fly host States do not understand why we treat fruit with X-Ray. By defining the purpose it would help them understand that the purpose of treatment is to keep unwanted pests from destroying agricultural crops or causing environmental destruction in certain areas of the United States.

It is possible that some unfavorable response might be made to this petition. Some anti-irradiation activists still believe that all irradiated food is unhealthy. They also believe more study should be done on nutrition depletion and other long-term effects of eating irradiated foods are warranted. The petitioner has also read material they circulate that indicates a concern that using X-Ray and E-Beam technology is a method to get irradiated products in demand to create a market for Cobalt 60 and Cesium 137. They may have objection based on their complete opposition to any further development of any food irradiation. Manufacturers of food irradiation systems that use Cobalt 60 or Cesium 137 may have objection to the petition. They may want all three technologies defined as one to avoid one technology gaining any greater consumer acceptance than the other.

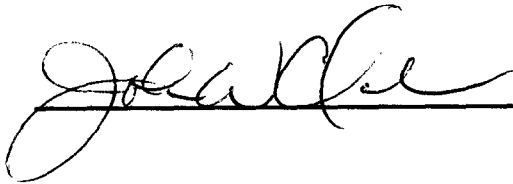
The Petitioner is unaware of any other unfavorable views that may exist.

Environmental Impact

I claim categorical exclusion under Secs. 25.30, 25.31, 25.32, 25.33, or Sec. 25.34 of this chapter or an environmental assessment under Sec. 25.40 of this chapter.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information on views, which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

A handwritten signature in black ink, appearing to read "John W. Clark", is written over a solid horizontal line that spans the width of the page.

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