

Public Citizen

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Joan Claybrook, President

July 3, 2001

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane — Room 1061
Rockville, MD 20852

Re: Docket No. 99F-4372, Food Additive Petition 9M4682

To whom it may concern:

Enclosed are materials that our organization presented to Joseph Levitt, Director of the Center for Food Safety and Applied Nutrition, and several other FDA staff members during a meeting held at the Parklawn Building on Wednesday, June 27. We request that these materials become part of the official record for this docket.

(1) A packet containing:

- A summary/cover sheet entitled "Food Irradiation and Cyclobutanones";
- two 1998 studies that examined the genotoxicity and cytotoxicity of cyclobutanones by Delincee, et al;
- an excerpt of a 1994 study by Stevenson that examined the use of alkylcyclobutanones as markers for irradiation;
- an excerpt from the 1980 Final Report of the FDA Irradiated Food Committee that discusses the need to study the potential carcinogenicity and mutagenicity of radiolytic products; and
- excerpts of two Federal Register notices that discuss the conditions under which radiolytic products would be considered in relation to the regulation of food irradiation.

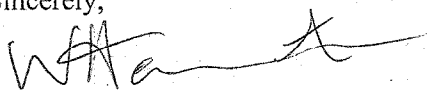
(2) A packet containing:

- A 1988 memo regarding studies used to support that FDA's 1990 decision to legalize the irradiation of poultry;
- A 1998 memo regarding studies used to support that FDA's 2000 decision to legalize the irradiation of eggs;
- An excerpt from a food additive petition to legalize the irradiation of "ready-to-eat" foods;
- An excerpt from a food additive petition to legalize the irradiation of molluscan shellfish; and
- An excerpt from a food additive petition to legalize the irradiation of crustacean shellfish.

(3) A packet containing:

- "Data Summary Forms for Irradiated Foods" produced by the FDA's Irradiated Foods Task Group in 1982, corresponding to nine of the positive studies cited in our comments filed for this docket dated May 14, 2001.

Sincerely,



Wenonah Hauter
Director, Critical Mass Energy and Environment Program

99F-4372

Ralph Nader, Founder

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