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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-5321]

United States Department of Agriculture, Food Safety and
Inspection Service; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY : The Food and Drug Administration (FDA) is announcing that the United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a 4.5 kiloGray (kGy) maximum dose of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products to reduce levels of foodborne pathogens and extend shelf-life.

FOR FURTHER INFORMATION CONTACT:

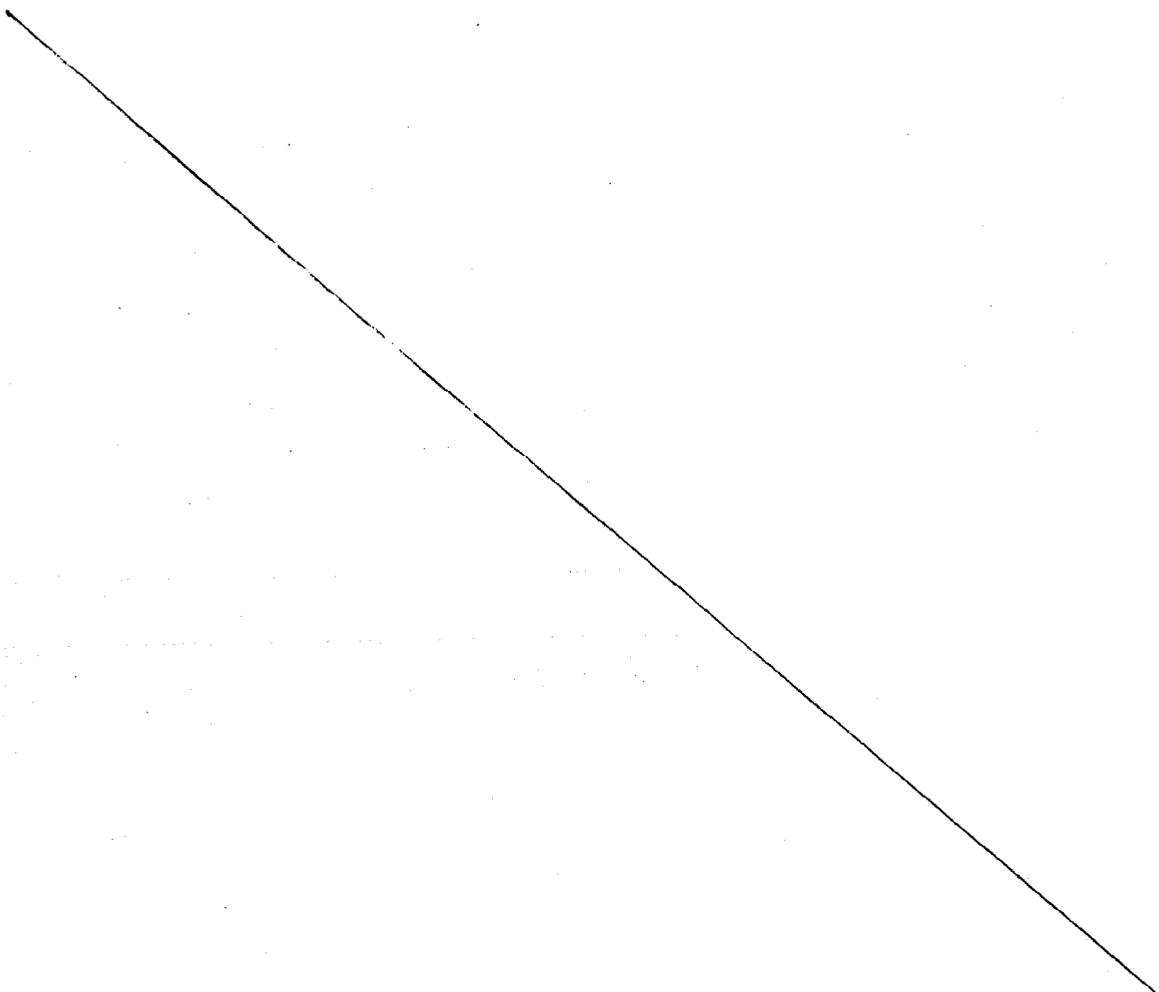
Rudaina H. Alrefai,
Center for Food Safety and Applied Nutrition (HFS-206),
Food and Drug Administration,
200 c St. SW.,
Washington, DC 20204,
202-418-3034.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9M4695) has been filed by the USDA/FSIS, 300 12th St. SW., rm. 112, Washington, DC

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20250. The petition proposes that the food additive regulations in § 179.26(b) Ionizing radiation for the treatment of food (21 CFR 179.26(b)) be amended to provide for the safe use of a 4.5 kGy maximum dose of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products to reduce levels of foodborne pathogens and extend shelf-life. The current regulations in § 179.26(b) provide for the use of a maximum dose of 4.5 kGy to treat refrigerated products only.

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.

Dated: Dec. 3, 1999
December 3, 1999

Alan M. Rulis

Alan M. Rulis
Director
Office of Premarket Approval
Center for Food Safety and Applied
Nutrition

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Michael W. Bell