§1262.307 Decision.

(a) The adjudicative officer shall issue an initial decision on the application with 90 calendar days after completion of proceedings on the application. The decision shall include written findings and conclusions on such of the following as are relevant to the decision: * * * * * *

§1262.309 [Amended]

6. In section 1262.309, last sentence, the word "amont" is revised to read "amount".

Dated: March 3, 1995. Daniel S. Goldin, Administrator. [FR Doc. 95–5669 Filed 3–7–95; 8:45 am] BILLING CODE 7510–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket Nos. 89F-0011 and 93F-0384]

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) is amending the food additive regulations to provide for the safe use of sources of radiation to irradiate frozen, packaged meats for use in the National Aeronautics and Space Administration (NASA) space flight programs. FDA is also amending the food additive regulations to permit the use of packaging materials that are not otherwise listed in the regulations regarding food irradiation in the irradiation of frozen, packaged meats for use in the NASA space flight programs. This action is in response to two petitions filed by NASA.

DATES: Effective March 8, 1995; written objections and requests for a hearing by April 7, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA– 305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS– 206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of February 6, 1989 (54 FR 5679), FDA announced that a food additive petition (FAP 9M4125) had been filed by NASA, Washington, DC 20546, proposing that the food additive regulations be amended to provide for the safe use of sources of radiation to process beefsteaks for use in space flight programs.

In a tentative final rule published in the Federal Register of December 8, 1993 (58 FR 64526), FDA announced its tentative decision to amend the food additive regulations to provide for the safe use of sources of radiation to irradiate frozen, packaged beefsteak for use in NASA's space flight programs. FDA also announced its tentative final decision to amend the food additive regulations to permit the use of packaging materials that are not listed in the regulations regarding food irradiation in the irradiation of frozen, packaged beefsteak for use in the NASA space flight programs. The agency published a tentative final rule before proceeding to final action because it was including provisions regarding the packaging materials to be used with the beefsteaks that it had not announced in the notice of filing for the petition (FAP 9M4125). Interested persons were given the opportunity to comment on FDA's tentative decision. FDA did not receive any comments in response to this tentative final rule.

In the meantime, in a notice published in the Federal Register of November 19, 1993 (58 FR 61093), FDA announced that a food additive petition (FAP 3M4394) had been filed by NASA, Lyndon B. Johnson Space Center, Houston, TX 77058, proposing that the food additive regulations be amended to provide for the safe use of sources of radiation to process certain prepackaged meats for use in NASA space flight programs and to permit the use of packaging materials that are not listed in the regulations regarding food irradiation in the irradiation of the meats for use in NASA space flight programs. Interested persons were given the opportunity to comment on the environmental assessment submitted in the petition. No comments were received.

The amendment to the food additive regulations proposed in FAP 9M4125 is encompassed by that proposed in FAP 3M4394. This rule is the agency's final decision with respect to both FAP 3M4394 and FAP 9M4125.

II. Evaluation of Safety

In assessing the safety of food additives, including the use of irradiation in the processing of food, the agency usually considers the effects of lifetime daily exposure to the additive. The requested use, however, is limited to NASA's space flight programs. The amount of irradiated meat that could be consumed by individuals in the programs would constitute an extremely small fraction of their diets when considered over a lifetime. Because of this factor, questions regarding acute hazards, including those resulting from pathogenic organisms that could be present in the food, are more significant in evaluating this petitioned use of a source of radiation than they would ordinarily be in deciding whether to list a food additive. The petitions have requested that FDA authorize the use of irradiation processing only under conditions that ensure the microbial sterility of the product and the integrity of the product packaging. NASA has stated that it will ensure these qualities of sterility and packaging integrity by requiring adherence to an irradiation processing protocol (scheduled process) that it submitted with both petitions (Ref. 1). NASA's protocol specifies a minimum dose of 44 kiloGrays (kGy) in order to ensure sterility of the treated meat (Ref. 1).

Having evaluated the data in the petitions and other relevant material in its files, the agency finds that radiationsterilized meats will be at least as nutritious as those sterilized by conventional means. FDA also finds that the total amount of radiolytic products that are produced in the meats during irradiation processing, and that will be consumed by individuals in the space flight programs, will be too small to be of any toxicological significance. Likewise, FDA finds that the total amount of radiolytic products that could be formed in the packaging materials during irradiation processing, and then migrate to the food and subsequently be consumed by individuals in the space flight programs, is too small to be of any toxicological significance (Refs. 2 and 3).

Section 179.25(c) (21 CFR 179.25(c)) restricts packaging materials used in the irradiation of prepackaged foods to those materials listed in § 179.45 (21 CFR 179.45), namely, those that have been demonstrated to be safe for use during irradiation of prepackaged foods, assuming that those foods would be consumed daily over a lifetime. The agency finds that this restriction is unnecessary for packaging that is to be used only in space flight programs. The