4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA-2018-F-3932]

Bonamar Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Bonamar Corp., proposing that we amend our food additive regulations to provide for the safe use of sources of ionizing radiation to control food-borne pathogens in finfish and flatfish.

DATES: The food additive petition was filed on September 27, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 8M4822), submitted by Bonamar Corp., c/o Robert P. Smith, Department of

Biological Sciences, Nova Southeastern University, 3301 College Ave., Fort Lauderdale, FL 33314. The petition proposes to amend the food additive regulations in § 179.26 (21 CFR 179.26) *Ionizing radiation for the treatment of food* to provide for the safe use of sources of ionizing radiation to control food-borne pathogens in: (1) chilled or frozen raw finfish and flatfish; and (2) frozen, raw vacuum-packed finfish and flatfish.

The petitioner has claimed that this action is categorically excluded from the need to prepare an environmental assessment or an environmental impact statement under 21 CFR 25.32(j), because the petition requests approval for a source of irradiation which is a piece of permanent equipment intended for repeated use. In addition, the petitioner has stated that, to the petitioner's knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-23946 Filed: 10/31/2018 8:45 am; Publication Date: 11/1/2018]