TABLE 1—INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PRODUCE SAFETY RULE DRAFT GUIDANCE DOCKET—Continued

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
<th>Electronic address</th>
<th>Address</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>View webcast</td>
<td>December 13, 2018; 8:30 a.m.–5 p.m.</td>
<td>Individuals who wish to participate by webcast are asked to preregister at <a href="https://www.fda.gov/Food-NewsEvents/WorkshopsMeetingsConferences/default.htm">https://www.fda.gov/Food-NewsEvents/WorkshopsMeetingsConferences/default.htm</a>.</td>
<td><a href="https://www.fda.gov/FoodNewsEvents/WorkshopsMeetingsConferences/default.htm">https://www.fda.gov/FoodNewsEvents/WorkshopsMeetingsConferences/default.htm</a>.</td>
<td>The webcast will have closed captioning.</td>
</tr>
<tr>
<td>Advance registration</td>
<td>by November 23, 2018.</td>
<td></td>
<td>We encourage you to use electronic registration if possible.</td>
<td>There is no registration fee for the public meetings. Early registration is recommended because seating is limited.</td>
</tr>
<tr>
<td>Submitting either electronic or written comments</td>
<td>Submit comments by April 22, 2019.</td>
<td><a href="https://www.regulations.gov">https://www.regulations.gov</a></td>
<td>Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.</td>
<td>See ADDRESSES for information on submitting comments.</td>
</tr>
<tr>
<td>Request special accommodations due to a disability</td>
<td>by November 16, 2018.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ADDRESS: 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 Fisheads 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.


Leslie Kux, Associate Commissioner for Policy.

BILLING CODE 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.

For further information contact: Christine K. Crockett, Office of Foods, Food and Drug Administration, 5001 Campus Drive, Rockville, MD 20852, 240–402–8052.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 1002, 1010, and 1040


RIN 0910–AG79 and 0910–AF87

Withdrawal of the Laser Products; Proposed Amendment to Performance Standard and the Electronic Submission of Labeling for Certain Home-Use Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is...