



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

*Rec'd in DMS
7/22/03 H.K.W.*

JUL 18 2003

Clyde A. Takeguchi, Ph.D.
Executive Vice President
Phoenix Regulatory Associates, Ltd.
Washington DC Headquarters
21525 Ridgetop Circle
Suite 240
Sterling, Virginia 20166

Dear Dr. Takeguchi:

This is in response to your letter of June 10, 2003, to Ms. Geraldine June, regarding the labeling of spice blends that contain irradiated ingredients. You specifically wanted to know whether the labeling of spice blends that are not irradiated but contain a component or a portion of the blend that was treated by irradiation, when shipped to food manufacturers for use in further manufacturing, be labeled with the statement, "Treated by irradiation, do not irradiate again." We hope that the following is helpful.

The requirement for labeling of foods that have been treated with irradiation are contained in Title 21 Code of Federal Regulations part 179. Section 179.26(c)(3) provides that for a food, any portion of which is irradiated, the label and labeling and invoices or bills of lading must bear either the statement "Treated with radiation-do not irradiate again" or the statement "Treated by irradiation-do not irradiate again" when shipped to a food manufacturer or processor for further processing, labeling, or packing. Therefore, the labels or labeling (e.g., invoices or bills of lading) of spice blends that contain portions that have been irradiated must include the statements, "Treated with radiation-do not irradiate again" or "Treated by irradiation-do not irradiate again" when shipped for further processing, labeling, or packing.

If you need further assistance, please don't hesitate to contact us.

Sincerely yours,

Loretta A. Carey
Consumer Safety Officer
Division of Food Labeling
and Standards
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

02D-0385

C17 /ANS

— PHOENIX —

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Rec'd
6/12/03

1397 '03 JUL 22 P1:41

June 10, 2003



Geraldine June, Supervisory CSO
Div. of Standards and Labeling Regulations, (HFS 822)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

VIA: email
original by mail

Re: Labeling of Spice Blends Containing Irradiated Ingredients

Dear Ms. June:

We have advised one of our clients that spice blends that has one or more of its components irradiated must be labeled with a statement, such as "Treated by irradiation, do not irradiate again" when shipped to a manufacturer or processor for further processing (21 CFR 179.26(c)(3)). Based on our advice, they have started to label their spice blends when one or more of the ingredients has been irradiated.

Now, some customers are questioning whether this label is required, and asking for a letter of clarification from FDA on this issue because not all suppliers are labeling their spice blends that contain an irradiated ingredient as "irradiated."

We are requesting a letter from FDA that clarifies the requirement for labeling of spice blends that are not irradiated but contain a component or a portion of the blend that was treated by irradiation, when shipped to food manufacturers for use in manufacturing or processing food.

Sincerely yours,

Clyde A. Takeguchi, Ph.D.
Executive Vice President
Phoenix Regulatory Associates, Ltd.