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Dockets Management Branch
(HFA-305)
Food & Drug Administration
530 Fishers Lane, Rm 1061
Rockville, MD 20852

January 10, 2001

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RE. Docket No. 99F-2673
Irradiation in the Production, Processing and Handling of Food.

In a letter dated November 9, 2000, I requested a hearing on the decision to allow for irradiation of seed for sprouting, without requiring a statement on the packaging that the seed has been irradiated.

This is in reference to:

**III. Labeling,
B.Sprouts Grown From Irradiated Seeds for Sprouting.**

I stated that this is contrary to other Federal regulations regarding sprouts in which the seed is considered to be the primary ingredient in the food, and sprouts are manufactured from the seeds. Based on these previous rulings, sprouts were classified as "food processing".

I have enclosed the January 18, 1982 advisory opinion, Sec. 555.750 (CPG 7120.28) upon which the FDA decisions have been based.

Specifically, "The FDA is of the opinion that all seeds used for sprouting are foods." And "seeds used for sprouting are too closely associated with the finished food (sprouts) to allow for an exemption of this type. In many instances, the spent bean hull is not even separated from the sprout before the sprouts are offered for sale as a finished food."

Based on this FDA opinion, the sprouts, and certainly the seed hulls, would be considered to have been irradiated and therefore a label indicating such should, by law, be on the package.

Sincerely,

Barbara A. Sanderson



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Treasurer

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99A-2630

Jonathan Sprouts, Inc.
170 Middleboro Road, E. Freetown, MA 02717

Sec. 555.750 Seeds for Sprouting Prior to Food Use, i.e., Dried Mung Beans, Alfalfa Seeds, etc.
(CPG 7120.28)

BACKGROUND:

An advisory opinion issued January 18, 1982 (Docket No. 80A-0518/AP), responded to the following issues:

1. Whether mung beans used exclusively for the purpose of growing bean sprouts should be regulated as "food," and
2. Whether, regardless of their ultimate classification, rodent-defiled mung beans to be used solely for growing bean sprouts may be exempt from sanitation inspections, seizure, and condemnation as an adulterated food.

The advisory opinion, although it specifically addressed mung beans, applies to other seeds that are used for producing sprouts for food use. The FDA has long held that mung beans are food. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f)) defines "food" as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such articles. Mung beans whether to be consumed in bean form or to be germinated to produce bean sprouts, are considered to be food. Although mung beans are not always consumed in bean form, they are still considered to be food if they are intended to be processed into food. USDA's classification of mung beans as seeds, not food, is not relevant to FDA's regulation of food under the act. FDA regulates many commodities as foods that are also used as seeds in growing crops. Corn, wheat, and dried beans, for example, have this dual identity, but these products are still regulated as foods. FDA is of the opinion that all seeds used for sprouting are foods.

FDA has, in the past, made some exemptions for foods used solely for seed purposes. Mercury-treated wheat is a case in point. A mercurial fungicide is permitted on wheat used for seed purposes only. However, in this case, the product of the growing process is separated from the seed by a complete maturation process that results in a separate food--the harvested wheat. Some similar exemption could be applied to mung beans used solely for the purpose of developing mature plants in order to harvest a crop of mung beans. However, seeds used for sprouting are too closely associated with the finished food (sprouts) to allow for an exemption of this type. In many instances, the spent bean hull is not even separated from the sprout before the sprouts are offered for sale as a finished food.

POLICY:

For the reasons stated above, FDA will regulate seeds used for producing sprouts for food and mung beans used exclusively for seed purposes, as food and cannot exempt them from sanitation inspections, seizure, and condemnation as adulterated food.

Issued: 7/15/82

Revised: 2/1/89

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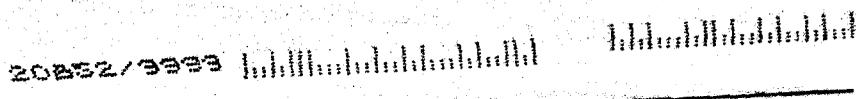
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