

HFI-35

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

REGULATORY LETTER

FEB 8 1991

Mr. Robert Fuhrman
President
C.R. Eggs, Inc.
842 First Avenue
King of Prussia, Pennsylvania 19406

FILE
COPY

Dear Mr. Fuhrman:

This letter concerns your continued marketing of "Heartland's Best" eggs in the face of our request that you cease marketing these high-iodine eggs because of the serious health concerns created by the excessively high levels of iodine. We have enclosed copies of our letters of November 21, 1990, and December 24, 1990, in which we expressed these concerns, for your ready reference.

In order to put this into proper perspective, let me share with you a brief summary of the information that we have concerning "Heartland's Best" eggs. We understand that "Heartland's Best" eggs will be produced by 26 selected franchisees with initial markets being set up by Weaver Brothers, Inc., Versailles, Ohio and Herbruck Poultry Farms, Saranac, Michigan. To produce these eggs, hens are fed a diet that contains a feed supplement ingredient called "Biotene" which consists of kelp, rice bran, alfalfa meal, Vitamin E and other ingredients. Biotene is blended for your company by Purina Mills and is available exclusively to licensed "Heartland's Best" egg producers.

We also understand that your firm approves and provides advertising and promotion material for "Heartland's Best" eggs. The labeling material we have seen from C.R. Eggs does not declare the presence of high levels of iodine in the eggs.

We understand that the addition of kelp, which is high in iodine, to the laying hens' diet at a level of approximately 0.15% results in eggs containing approximately 170 micrograms (ug) of iodine per egg. We have objected both to the use of kelp in laying hen diets and to the marketing of high-iodine eggs in our December 24, 1990, letter to you. In that letter, we advised you that the use of kelp in feeds for the purpose of increasing the iodine content of eggs or affecting the blood cholesterol level of humans consuming the eggs is in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) because the kelp is a food additive within the meaning of section 201(s) and has not been approved for this use under section 409 of the Act.

As we previously advised you, we are very concerned about the

adverse effects of elevated iodine intake from the high-iodine eggs produced by your firm.

Iodine toxicity may occur in certain susceptible persons following consumption of high-iodine eggs. The iodine content of eggs produced by C.R. Eggs, Inc. is reported to be 170 ug/egg. In contrast, the iodine content of eggs is normally 4-10 ug/egg. Adverse effects of iodine have been reported to occur following intakes as low as 400-500 ug/day in such persons. The iodine level in the U.S. food supply has already been shown to exceed by four times the Recommended Dietary Allowance (RDA) of 150 micrograms in adults and more than six times the RDA of 70 micrograms in children. Thus, the consumption of just one of your high-iodine eggs would contribute an additional RDA for iodine in an adult; and, two high-iodine eggs, the recommended serving, would raise the iodine intake for some individuals to more than six times the RDA. One of your high-iodine eggs would contain over four times the infant RDA.

Adverse effects of excess iodine from food sources include thyroiditis, goiter, hypothyroidism, hyperthyroidism, and acneiform or other cutaneous eruptions.

Particularly susceptible groups include persons with the following conditions or characteristics: thyroid disorders, iodine sensitivity, neonates born to mothers with high iodine intakes during pregnancy, neonates nursed by mothers with high iodine intakes, pregnant women, and persons with previous low iodine intakes who are exposed to substantially increased iodine intake. Of additional concern would be the effect of increased iodine consumption by women during pregnancy. Excess iodine may suppress development of fetal thyroid tissue and thus induce thyroid disorders in these children.

Thus, consumption of the high-iodine eggs would be expected to significantly increase the risk of thyroid problems in susceptible persons.

Our review of the labeling and promotional materials for C.R. Eggs, Inc. "Heartland's Best" eggs has revealed continuing serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
402(a)(1)	"Heartland's Best" eggs contain the added substance iodine at levels which may render these eggs injurious to health.
403(a)(1)	The article contains the added essential nutrient, iodine, but fails to bear nutrition labeling as required by 21 CFR

101.9.

The labeling fails to state the material fact that the claim "Heartland's Best eggs will not increase blood serum cholesterol" and that "in clinical tests in which people ate 12 Heartland's Best eggs per week, as part of a well-balanced, low-fat diet, total cholesterol actually decreased significantly" is based on elevated levels of the iodine in the eggs, and that elevated iodine levels may be unsafe for various groups of people.

The cholesterol reduction claims have not been adequately established.

The heart symbol (on the eggs and packaging) and labeling (placard) statements "will not increase blood serum cholesterol", "people enjoying the Heartland's Best eggs actually reduced their cholesterol about as much as those on the low-fat diet alone", "in clinical studies as part of a low-fat diet, even 12 Heartland's Best eggs a week caused no increase in serum cholesterol", and "our eggs will help you watch your cholesterol in one way oat bran just can't - deliciously" falsely represents and suggests that the addition of "Heartland's Best" eggs to your diet will produce a meaningful and sustained reduction in serum cholesterol.

As stated in our letter to you on December 24, 1990, the use of kelp in laying hen feed for the purpose of increasing the iodine content of eggs or affecting the blood cholesterol level of humans consuming the eggs makes the kelp a food additive within the meaning of section 201(s) that has not been approved for this use under section 409 of the Act. A food additive petition should be submitted, pursuant to 21 CFR 571.1, if you believe that safe use can be demonstrated in view of the high levels of iodine already present in the food supply.

We request that you take prompt action to correct the above violations. If such action is not taken, the FDA is prepared to invoke the regulatory sanctions under the law. These include seizure and/or injunction.

Please notify us within 10 days of the steps you have taken to correct these label claims. If corrective actions cannot be completed within 10 days, please provide the reasons for the delay and the time within which the corrections will be completed. Your

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response should be directed to: Charles B. Thorne, Compliance Director, Food and Drug Administration, Philadelphia District, U.S. Customhouse, 2nd and Chestnut Streets, Room 900, Philadelphia, PA 19106.

Sincerely yours,

Alan L. Hoeting

Alan L. Hoeting
Director,
Office of Enforcement

Enclosures:

1. November 21, 1990, letter Fuhrman/Lake
2. December 24, 1990, letter Fuhrman/Mitchell



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFV-200
Public Health ServiceFood and Drug Administration
Rockville MD 20857

NOV 24 1990

Mr. Robert Fuhrman
President
C.R. Eggs, Inc.
842 First Avenue
King of Prussia, Pennsylvania 19406

Dear Mr. Fuhrman:

Based on our review of your letter of November 1, 1990, to L. Robert Lake, and of the material that accompanied it, we do not agree that the feeding of kelp to laying chickens at approximately 0.15% of their diet is generally recognized as safe (GRAS). According to the information you provided, this feeding of kelp would result in eggs containing approximately 170 micrograms of iodine. The iodine level in the U.S. food supply has already been shown to exceed by four times the Recommended Dietary Allowance (RDA) of 150 micrograms in adults and more than six times the RDA of 40 micrograms in children. Thus, the consumption of just one of your high-iodine eggs would contribute an additional RDA for iodine in an adult; and, two high-iodine eggs, the recommended serving, would raise the iodine intake for some individuals to more than six times the RDA. One of your high-iodine eggs would contain over four times the infant RDA. In our view, that level would likely present a significant risk to some individuals.

Because of this safety concern, the use of kelp in feeds for the purpose of increasing the iodine content of eggs or affecting the blood cholesterol level of humans consuming the eggs is in violation of section 402 (a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), because the kelp is a food additive within the meaning of section 201(s) and has not been approved for this use under Section 409 of the Act. While we do not know that safe use can be demonstrated because of the presence of high levels of iodine in the U.S. food supply, we will be willing to assist you in preparing a food additive petition pursuant to 21 CFR 571.1.

We have not completed our review of all the information accompanying your November 1 letter. Nevertheless, we are concerned about the implied claim that consumption of your high-iodine eggs will not raise blood cholesterol levels although these eggs contain normal levels of cholesterol. You will receive further communication from us on this matter.