



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Robert Byrne  
National Milk Producers Federation  
2101 Wilson Blvd.  
Arlington, VA 22201

APR 18 2000

Food and Drug Administration  
Washington DC 20204

F00-5740

Dear Mr. Byrne:

In response to your request of March 17, 2000 for specific listed letters related to FDA positions regarding the use of the term "soymilk" or similar dairy-type terms in the labeling of certain food products.

XX Enclosed are the records you requested.

       We have searched our files and find no responsive information.

       Your request is also being referred to one of our component offices.

In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address: Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal.

Charges will be included in a monthly invoice if your request(s) total more than \$15.00. If your monthly total is LESS than \$15.00, the material is free. Please DO NOT send payment until you receive an invoice for the total monthly fee.

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THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.

Sincerely yours,

FOI OFFICER  
Executive Operations Staff  
Center for Food Safety  
and Applied Nutrition

Enclosure

January 23, 1981

Mr. Eisuke Murakami, President  
K. Tanaka & Company, Inc.  
5995 Riverdale Ave.  
Riverdale, N.Y. 10471

Dear Mr. Murakami:

This is in reply to your letter of 12/18/80 concerning the importation of your soybean product.

The statement "soybean milk" has not been sanctioned as an acceptable identity statement for such a mixture as water, soybean, wheat and served by this agency. While the terms soy milk, soybean milk, etc. has been used in the past, it has been used to represent products consisting of water and ground soybean to water and components of soybean and other food ingredients. Therefore, is not a clear and uniform understanding of what "soybean milk" is in this country.

Additionally, your letter failed to indicate whether your product is intended to substitute for milk of some other traditional product, and/or whether the product is thermally processed and packed in hermetically sealed containers.

If you would provide a complete listing of all of the ingredients in this product by their common or usual names, including water, and seasoning; an explanation as to what the ingredient "declared as 'Job's Tears wheat'" is; information as to how the product is packaged; method of processing; and a mock-up label for the product we will comment with more completeness.

Sincerely yours,

James L. Summers  
Assistant to the Director  
Division of Regulatory Guidance  
Bureau of Foods

SEP 29 1983

Air Mail

Mr. Kok Ee Lynn  
Senior Officer  
Food Technology and Microbiology Section  
Singapore Institute of Standards and Industrial Research  
179 River Valley Road  
Singapore 0617  
Republic of Singapore

Dear Mr. Lynn:

This is in reply to your August 3 letter concerning soy milk and soy bean drink.

We have no regulations that pertain specifically to soy milk and soy bean drink. Further, we have not recognized the term "soy milk" as a common or usual name or appropriately descriptive term for statements of identity or ingredient designations of any food. As a result, we would object to any soy product entering this country that was labeled as "soy milk". The term "soy bean drink" could serve as a statement of identity for some soy products if their basic nature and ingredients would support such a statement. However, we would need to review the specific product and its labeling in order to give meaningful advice in this area.

If we can be of further assistance, please let us know.

Sincerely yours,

James R. Taylor, Jr.  
Assistant to the Director  
Division of Regulatory Guidance  
Bureau of Foods

Y Milk -  
Soy Bean Drink

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VIA AIR MAIL

C. Hwang  
Overseas Business  
Department Manager  
Dr. Chung's Foods Co., Ltd.  
10th Floor, Kinam Building  
San 75-31, Yeoksam-Dong  
Kangnam-Ku, Seoul, Korea

Dear Mr. Hwang:

This replies to your letter of June 7, 1985, concerning soy beverages that you wish to import into the United States.

Concerning the containers used for these products, we have serious concerns as to the ability of the procedures used during start up to bring the Combi-bloc's aseptic filling and closing areas to a state of commercial sterility before beginning filling and closing operations. Likewise, we have concerns as to whether the Combi-bloc's aseptic filling and closing areas can be maintained in a state of commercial sterility during production. Therefore, until such time as we have acceptable evidence that the procedures used ensure that the Combi-bloc packaging system can be brought to a state of commercial sterility prior to the start of production and maintained in a state of commercial sterility during production, foods packaged in Combi-bloc containers will not be permitted into the country.

For your information, we are presently in contact with representatives of Combi-bloc and they are aware of our concerns. Should you wish to proceed in this matter it would appear appropriate for you to contact your Combi-bloc technical representative, or some other process authority, and attempt to develop data that would respond to our concerns. Any acceptance of a process filing form by this agency would be predicated on the submission of data that demonstrate proof of both machine and container sterilization.

If the problems with the container are resolved, you will need to revise almost completely your product labels and the promotional pamphlet and booklet. We cannot evaluate most of the label statements since they do not appear in English.

PACKAGE LABEL:

1. The names "soymilk" and "vegetable milk" are not acceptable identity statements for these products. The product may be called "soy drink" or "soy beverage."



2. The net contents statement must be declared in fluid ounces and the statement must be located in the lower 30% of the principal display panel. The type size of the letters must be not less than 1/8 inch in height for this size container. (21 CFR, 101.125). We do not object to the metric statement as a supplemental declaration.

3. Claims pertaining to the vitamin, mineral, or protein content trigger nutrition labeling under 21 CFR, 101.9.

4. "Long life," which appears on the top surface of the container is misleading since it implies that consumption of the product will result in increased longevity.

5. "Woorean" is not a familiar term and may be misleading.

6. All mandatory labeling must appear in the English language.

PAMPHLET ("Advantages of ...Soy Milk"):

Practically the entire text is misleading and contains exaggerated or questionable claims about the attributes of these products and their effects on cholesterol, acidification, diarrhea, lactose intolerance, prevention of "nervous breakdown, languor, neuralgia, high blood tension, hardening of the artery," and similar claims.

We are particularly concerned about the references to the suitability of these products for infants who are allergic to milk. They may not be safely substituted for infant formula since they do not contain the nutrients required in infant formula.

The labeling of soy beverages is currently under review by the agency to determine if warning statements may be necessary to warn consumers that they may not be used as substitutes for infant formula. If our evaluation indicates a need to require such warnings, your products will be subject to the requirement.

BOOKLET ("Chung's Foods offers health..."):

The text contains exaggerated and questionable claims about the nutritional qualities of the products and false and/or misleading claims about the products' positive effects on cholesterol level, controlling "body acids," prevention of aging skin, and other claims.

INGREDIENT LIST (Attached to letter):

1. Amino acids may not be added to foods except under the conditions of 21 CFR, 172.320. You will need to demonstrate that the addition of methionine is in accord with those requirements.
2. If saccharin is being added as a sweetener in the chocolate flavored drink, its use must result in a food which has at least one-third fewer calories than a similar product sweetened with nutritive carbohydrate sweeteners and otherwise comply with the provisions of 21 CFR, 105.66.
3. We are not familiar with the ingredient "silicone oil."

Copies of the above referenced regulations are enclosed for your information. We hope these comments are helpful.

Sincerely yours,

Lillie Taylor  
Assistant to the Director  
Division of Regulatory Guidance  
Center for Food Safety  
and Applied Nutrition

Enclosures

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