



28 MAR 2003

Ms. Ruth Schneider
43124 M-43 Lot #306
Paw Paw, Michigan 49079

Dear Ms. Schneider:

This responds to your letter, dated January 30, 2003, to the Food and Drug Administration (FDA) requesting that FDA require manufacturers to list on product labels all ingredients in the foods they produce, including the sources of "natural flavors." You explained in your letter that you have a food allergy to milk and an intolerance to citric acid. Therefore, you closely read the ingredient lists to avoid purchasing foods that could cause you problems. You stated that you have purchased food products in the past that you thought were milk free, but later discovered they contained an ingredient derived from milk that was listed on the label as a "natural flavor." You indicated that a food company representative told you that ingredients representing less than 2 percent of a food product did not have to be listed on the label, and you urged FDA to require complete ingredient listing for all foods.

First, we would like you to know that FDA has a major food allergy initiative underway to make food labels more helpful to persons who have food allergies. One of FDA's priorities in fiscal year 2003 is to develop a proposed rule to require manufacturers to clearly identify in the ingredient list on food labels the presence of any common food allergens. We fully understand the importance of making this type of information available to allergic consumers.

Any rule FDA proposes will be published in the *Federal Register* and will solicit public comments. You will be able to access any rule we propose on the topic of food allergen labeling at FDA's Internet Web site at <http://www.cfsan.fda.gov/~dms/wh-alrgy.html>. A printout of the information about food allergens available at this Web site is enclosed for your reference.

Second, we would like to clarify for you FDA's basic food labeling requirements in effect today, including use of the term "natural flavors" and how ingredients may be listed that are present in very small amounts, such as 2 percent or less of the food's total weight. Currently, Federal laws and regulations require that the labels of food products sold in the United States provide a complete listing of all their ingredients with two exceptions.

OOP-1322

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One exception, found in the law, to this requirement is that spices, flavorings and colorings (other than certified colors) may be declared collectively on the label without naming each one. This exception directly relates to the issue you raised about the use of the term "natural flavors" in the ingredient list without identifying each flavor's origin, such as milk. Since some natural flavors may be derived from food allergens, they can pose a risk to allergic consumers. We are aware that Congress is considering legislation to amend the Federal Food, Drug and Cosmetic Act to require labels of food products to clearly identify in easy-to-understand language any common food allergens they contain.

A second exception, found in FDA regulations, to this requirement is that incidental additives, such as processing aids, used in the manufacture of foods would not have to be listed on the label if they are both: 1) present at insignificant levels, and 2) do not have a technical or functional effect in the finished food. Because evidence indicates that even very small amounts of food allergens can cause serious adverse reactions in allergic consumers, FDA does not consider the presence of a food allergen in a food to be "insignificant." Therefore, food allergens, otherwise considered as processing aids, cannot meet the requirements of this exception, and should always be declared in ingredient lists of food labels.

On June 10, 1996, FDA issued a letter to food manufacturers reminding them that they should clearly identify the presence of food allergens used as ingredients on their product labels. The letter also reminded manufacturers of the need to adhere to good manufacturing practices to prevent the unintended addition of food allergens in their products. This letter and other guidance materials FDA has developed for the food industry and FDA food inspectors are posted at the Web site noted above.

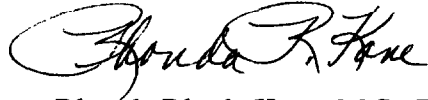
We would like to point out that FDA regulations require that each food ingredient be listed by its common or usual name on the label in descending order of predominance by weight. This means that the ingredient contained in a food that weighs the most is cited first in the ingredient list, followed by the second heaviest ingredient, and so on down to the last ingredient listed that weighs the least. However, this descending order of predominance requirement does not apply to ingredients weighing 2 percent or less of a product's total weight. Instead, such ingredients can be grouped together, in no particular order, at the end of an ingredient list, provided that they are preceded by an appropriate statement like "Contains 2 percent or less of" followed by the common or usual names of the individual ingredients.

In closing, we want you to be aware that FDA has received a citizen petition (docket number 00P-1322) from nine State Attorneys General that raises concerns similar to yours about the use of collective terms like "natural flavors" in ingredient lists and the need for uniform and consistent allergen labeling. This petition is posted at FDA's Docket Management Branch (Dockets) at <http://www.fda.gov/ohrms/dockets/dailys/00/may00/053100/cp001.pdf>. We will forward your letter to Dockets to be included with other letters responding to this petition. Please be assured that FDA will consider all comments before making a final decision on what action to take on this issue.

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Thank you for taking the time to share your thoughts with us. It is helpful to FDA to receive feedback from consumers, like you, who depend upon the information found on food labels to avoid purchasing products that might contain allergens.

Sincerely yours,

A handwritten signature in cursive script that reads "Rhonda R. Kane".

Rhonda Rhoda Kane, M.S., R.D.
Consumer Safety Officer
Regulations and Review Team
Division of Food Labeling
and Standards
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

**U. S. Department of Health & Human Services
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition**

Information about Food Allergens

Information on Food and Nutrition from FDA

- FDA Food Labeling and Allergen Declaration; Public Workshop - August 14-15, 2002 in Dallas, Texas
 - Announcement
 - Registration Form (also available in PDF)
 - Federal Register Notice of Public Workshop March 29, 2002 (also available in PDF)
- FDA Public Meeting on August 13, 2001: The Challenge of Labeling Food Allergens July 24, 2001
- Food Allergies: When Food Becomes the Enemy July-August 2001
- Letter on Food Allergen Labeling Guidelines May 30, 2001
- **Allergen Guides**
 - Dear Colleague Letter on Allergen Guides May 3, 2001
 - Questions and Answers on Allergen Guides May 3, 2001
 - Compliance Policy Guide: "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" April 19, 2001
 - Inspection Guide: "Guide to Inspections of Firms Producing Products Susceptible to Contamination with Allergenic Ingredients" August, 2001

- Food Allergen Inspection Training for Regulators October 5, 2001
 - Conducting Food Allergen Inspections (training videos)
- Food Allergen Partnership January 2001
 - Letter About the Food Allergen Partnership March 2001
- Food Allergen Awareness: An FDA Priority February-March 2001 (also available in PDF)
- The FDA, Food Allergens and You Audio Slide Presentation November 2000
- Food Allergies: Rare but Risky May 1994
- Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers June 1996

Information from Other Federal Government Agencies

- Department of Health and Human Services Healthfinder
 - Food Allergies

- National Institute of Allergy and Infectious Diseases
 - Food Allergy and Intolerances Fact Sheet

- National Library of Medicine
 - Food Allergy (Medical Encyclopedia) ^{NEW}
 - Food Allergy (MEDLINEplus)

Updated Jan. 27, 2003

Women's Health

ROUTING SLIP
GENERATED BY: HF-40
DATE: MAR 03, 2003

FDA CONTROL NUMBER: 03 976

TRACER #: **OS #:**

DATE OF CORRESPONDENCE: 01/30/03

DATE INTO FDA: 03/03/03

TO: FDA, FOOD AND DRUG ADMINISTRATION

FROM: RUTH TODD SCHNEIDER

SYNOPSIS: WRITES CONCERNING FOOD LABELING DUE TO ALLERGIES.

LEAD OFFICE: HFS-1

HOME OFFICE: HF-40

CONTACT/PHONE#: KELLY M MALONE 301-827-4437

COPIES:

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HFS-1	PREPARE DIRECT REPLY	04/03/03
REMARKS: PLEASE SEND COPY OF RESPONSE TO KELLY MALONE, HF-40.		

Send to ONPERS

Jan. 30, 2003

F.D.A. Corporate Offices
Office of the Commissioner
5600 Fisher Lane
Rockville, M.D. 20857

Dear Sir/Madam:

Just what does a person with allergies have to do to convince you to crack down on food manufacturers and force them to list everything contained in their product instead of using the umbrella listing of "natural flavors?" I, personally, have an allergy to milk products and an intolerance to citric acid. And, because these mfrs. are constantly changing their ingredients, I am forced to read these lists every time I shop for food which is usually 2 or more times weekly. I've been doing this since 1955 which is 48 years!

This past September I got hold of something with milk in it. Fortunately I don't go into anaphylactic shock BUT if ingested (even a miniscule amount) it usually takes 2 weeks to leave my system.

Just recently I purchased a Duncan Hines cake mix...no milk was listed but a "D" appeared on the box which stands for "dairy." Also was the abominable listing of "natural flavors." Sometimes, even though there is no milk or peanuts in the mix itself, the mfrs must list it under the guise of "D" because it could be in the air or on conveyor belts while making other products and may have fallen into these mixes! Are these kitchens sanitary enough?

So, I bought the mix with the "D" on it hoping it was "in the air" and not in the mix and called Hines Co. I was told that under the "natural flavors" listing there really was milk in the mix BUT they also told me that if the amount is under 2% they do not have to list it! Therein lies my problem not to mention my nemesis! I am not just "a little bit allergic" - that would be like saying "I am just a little bit pregnant!"

Several months ago I found an imitation cheese (Veggie Kaas) which ~~prints~~ ^{claims} 100% milk free - HA! I ate it (even though there was the "natural flavor") listing and paid the price because ~~xxxxx~~ there was 2% of a milk product in it. How can you allow this to happen? That's not only misrepresentation in advertising (which is illegal) but could be dangerous to some.

Several months ago I called Ms. Evelyn Denike at the FDA center for Food Safety & Nutrition in Detroit. She was real nice and sympathised and said she would contact you to see if there was anything you not only could but would do to help those of us unfortunates that have allergies. The wheels of progress are bogged down!

Your comments would be appreciated but your crack-down would most welcome. An SASE is provided for your comments. Thank you. And, please forgive all the typos.

Sincerely yours,

Rud Schneider

269-657-7119

03-976