



APR 16 2004

Ms. Anne Muñoz-Furlong
Founder and CEO
The Food Allergy & Anaphylaxis Network
11781 Lee Jackson Highway, Suite 160
Fairfax, Virginia 22033-3309

Dear Ms. Muñoz-Furlong:

This responds to your letter, dated January 21, 2004, to Mr. Joseph Baca, Director, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA). Your letter expressed the concern of The Food Allergy & Anaphylaxis Network (FAAN) about the current use of the term "non-dairy" on labels of food products, including those that may actually contain a milk protein-derived ingredient.

Your letter states that based upon FAAN surveys and other communication your organization has received, many FAAN members are confused about the meaning of the term "non-dairy" used on food labels of products that serve as imitations or substitutes for traditional milk-based products. You report that FAAN members frequently misinterpret this term to literally mean "no dairy," or no use of any dairy-derived ingredients, most especially milk protein-derived ingredients (e.g., sodium caseinate) that must be avoided by persons who have a food allergy to milk. As a result, if milk-allergic consumers select products with a "non-dairy" statement on the label that actually contain a milk protein-derived ingredient without also reading the statement of ingredients, they may mistakenly eat the product and suffer a life-threatening allergic reaction. You urged FDA to help find a solution to this predicament.

As you may know, the term "non-dairy" or "nondairy" used on food labels is not defined by FDA regulations. Instead, State laws and requirements regulate when and how this term can be used on food labels. However, FDA regulations at Title 21 of the Code of Federal Regulations (CFR) §101.4 require that when such a term appears on the label of a food that contains a caseinate ingredient such as sodium caseinate, the common or usual name of such an ingredient must be immediately followed parenthetically by the words "a milk derived ingredient" or similar language in the statement of ingredients to clearly identify "milk" as its source. Consequently, a product labeled as "non-dairy" is required to disclose in the list of ingredients in plain English terms the fact that any caseinate ingredients present originate from milk. Nevertheless, the information you shared in your letter indicates that some consumers may still be misled by the use of the term "non-dairy" on labels for foods that actually contain a milk protein.

Because laws at the State rather than Federal level currently influence the use of a "non-dairy" statement on food labels, FDA would be willing to contact representatives of such States to discuss FAAN's concern with them. To help facilitate this discussion, we would like to know if we could share a copy of your January 21st letter along with its enclosures with our State partners so FDA can more accurately and fully describe the problem with the current use of this term for

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milk-allergic consumers. We believe that this Federal-State dialog is an essential first step to pursuing a possible remedy.

You are invited to call me at (301) 436-2371 to inform me if it would be agreeable to you if FDA provided copies of your letter to our State contacts. We also plan to submit a copy of your correspondence and this response to FDA's Division of Dockets Management to file it as a comment related to docket #00P-1322 which pertains to citizen petitions FDA received earlier about the issue of food allergen labeling.

Thank you for conveying specific information on the confusion experienced by some milk-allergic consumers about the current use of term "non-dairy" on food labels. FDA looks forward to working with our State cooperators to try to find an effective solution to this problem.

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
Food Labeling
and Standards Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



January 21, 2004

Joseph R. Baca
HFS-600 Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Joe,

The Food Allergy & Anaphylaxis Network (FAAN) would like to notify you of a problematic food labeling issue: the use of the term "*non-dairy*" on certain food items that contain milk-derived proteins such as *casein* or *caseinate*.

Under current food labeling laws, casein or caseinates are considered chemical additives. As a result, foods that contain these ingredients can be legally advertised as "non-dairy" products.

As you may know, *milk* is one of the 8 major food allergens, and is most common among young children, with an estimated 2.5% of children under the age of 2 affected.

There is no cure for food allergy. Only strict avoidance of the allergen will prevent an allergic reaction. As a result, reading and understanding ingredient labels is critical in avoiding the offending allergen.

Many of our members have told us they have purchased "non-dairy" products for their milk-allergic children because they believed these items to be safe. Individuals often interpret "non-dairy" to mean "no dairy" and therefore do not feel it necessary to read the ingredient statement on the back of the package. In fact, doctors often advise parents of milk-allergic children to avoid "milk", without informing the patient/parent of technical ingredient names such as casein.

FAAN has learned of situations in which "non-dairy" items (such as whipped toppings, imitation cheeses, and soft-serve frozen desserts) have caused milk-allergic reactions in children because it was later discovered that the item contained a milk-derived protein. Sometimes, this discovery was not made until *after* the child had ingested the food, suffered an allergic reaction, and was treated by 911 rescue personnel.

Clearly, this is a situation that no parent should have to face. However, until the confusion between *non-dairy/casein* is settled, this scenario will continue to play out in the future.

FAAN urges FDA/CFSAN to help remedy this potentially fatal state of affairs.

Enclosed you will find: a letter written to FAAN detailing one mother's tragic experience with the term "non-dairy"; and consumer survey responses on the issue of "non-dairy".

Thank you for the opportunity to express our concerns on the "non-dairy" issue.

Please feel free to contact me at your convenience. I look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Anne Muñoz-Furlong". The signature is fluid and cursive, with a large loop at the end.

Anne Muñoz-Furlong
Founder and CEO

Cc: Felicia B. Satchell, HFS-820

Dear Anne,

Being the mother of two wonderful children, Brandon 4 (allergy free) and Lindsey 2 (**highly-allergic**) has been a blessing. Shortly after Lindsey was born, I knew something was not right. She was always congested, swollen in the face and lacked bowel movements. We eventually found out at seven months of age, she was allergic to: wheat, dairy, egg, peanuts, tree nuts, kiwi, barley, and mustard. As a family we were devastated and in shock. Since she was exclusively nursed, her diet became my diet.

After her diagnosis, we tried to do all the right things. We read books, became FAN members, cooked safe, educated family, joined a support group and then started one of my own. In June of 2002, our diligent efforts were almost for nothing. Lindsey, at 16 months of age, was given two slices of non-dairy cheese. Lindsey's father read the cover of the cheese which stated "**Non-dairy**". He thought it was safe. It was not. After reading the label further he realized this product contained **casein**.

Shortly after she consumed the cheese, she became extremely irritable. As her irritability grew worse, she then began to swell, wheeze and gasp for air. At this time we were in a state of panic. At this moment I thought my beautiful, little sixteen month old was going to die. She became limp and struggled with each breathe. I recall screaming from my kitchen, "We need epi, we need epi." When my husband came back into the kitchen, we followed correct medical protocol: Epinephrine, Benedryl and then 911. Never having to use epinephrine before, I did not realize how it worked. While we waited for our local rescue squad (which seemed like forever) her airway began to open. As I stood on my front lawn, I remember never wanting to ever experience this again nor should anyone else have to have these same feelings.

Upon arriving at the hospital, Lindsey was given even more medication. Because of all the medicine she received, she became as pink as a flamingo which scared me all the more. In consulting with the emergency room doctor, she said her color change was normal due to the medications. None of this was or should be normal for any family. The reality of what happened did not hit me until I spoke with her nurse. She gently explained to me, "You saved her life." After giving birth to her just 16 months earlier, I never thought I would need to save it.

After living with these feelings for a year, I can now share our story with tears in my eyes. I hope with new FDA regulations **casein** will be taken off the chemical list and be put onto the correct one- **dairy**. As defined in the Webster's Dictionary, "**casein is a protein that is one of the chief constituents of milk.**" This **protein** can be deadly and should be categorized in the correct way. This simple change could potentially save lives.

I hope our story will help the FDA in regards to their efforts for better labeling on food products. Thank you for your time and consideration. Contact me with any further questions at 732-821-0567 or bmwlaw123@aol.com.

Sincerely,
Dina Warick
32 Paul Avenue
Kendall Park, NJ 08824

**Written Comments on “Non-Dairy” & “Dairy-Free”
(taken from FAAN’s 2000 patient conference surveys)**

1. Contains milk products
2. Use of false statements i.e. Dairy free when not true
3. Non Dairy is misleading
4. Non-dairy label is not true – confuses friends & family
5. Dairy – Free issue
6. Non-dairy – isn’t
7. Most products labeled non-dairy have casein! Yikes!
8. When something is labels i.e. (U)D <- What dairy does it have if no dairy products are listed in the ingredients
9. Why are foods misrepresented on front non-dairy
10. Why dairy-free is used on products that still contain milk or derivatives of milk
11. If it has dairy of any kind – should not say non-dairy
12. Non-dairy when it does contain milk product/protein!
13. Products containing milk protein being labeled non dairy
14. Too many variables – vocabulary, percentages DAIRY FREE – not
15. Having non-dairy foods truly be non-dairy!!
16. Non-dairy in big letters on front, casein in small print on back
17. Non-Dairy in front of package – ingredients list dairy or casein/whey
18. How can something be labeled in large print on front of label as Non-Dairy and then in small print on ingredient label have milk/casein/whey noted?
19. Non-Dairy does not mean dairy free completely & people don’t realize this. It is dangerous.
20. Mistakes – Non-dairy Dairy-free – get some (an Act a bill) regulations in place!
21. Non-dairy label containing milk
22. Calls itself dairy free when it contains casein (e.g. Coffeemate, cool-whip)
23. Non-dairy cool whip etc. That is not non-dairy
24. Non-Dairy – when product contains dairy/milk protein
25. Non-dairy products always contain milk-derived ingredients
26. Products that states dairy free (but actually label states lactose, etc.)
27. Dairy free labels that contain milk derivatives
28. Non-dairy labels on front of product, but dairy products on ingredients
29. Non-dairy on front of package, but dairy on ingredients
30. Can’t have other people read – too complicated when says non-dairy but really does contain milk!
31. Different names for same product * states non-dairy on package, but dairy is listed or an ingredients
32. Why does it say milk free if its not
33. Not listing a food allergen because company feels it is not at an allergic level ex. Non-dairy on front yet contains milk products
34. Non-dairy when it contains dairy
35. Casein issue product may say dairy free but contain casein
36. Inappropriate use of term non-dairy

37. Non-Dairy? = then dairy in there
38. Why are non-dairy products that actually do contain some dairy products
39. Misleading labels like non-dairy
40. Use of the term non-dairy on packages
41. How can products such as cool-whip be allowed to print non-dairy on its product when it in fact it does contain sodium caseinate – a milk derived protein?
42. No false labeling – cannot use term non-Dairy if contains milk!
43. Why & casein not called milk (using non-dairy) on front of package
44. Non-dairy should not be used on label if milk is an ingredient
45. Non-dairy issue on labeling – misleading
46. Honesty of labeling: non-dairy, peanut free, etc. Must really mean this!
47. Why can an item be labeled non-dairy if it has dairy in it
48. Why are some products that contain some dairy labeled non-dairy
49. Dairy Free labeling when in fact it's not
50. Non-dairy but contains dairy labeling
51. Non-dairy label can contain dairy
52. Non-dairy but contains dairy labeling
53. Dairy free is misleading
54. Cool whip claims to be non-dairy however whey is listed on the label – How can they claim non-dairy?