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By Hand Delivery

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 2000P-0586 (formerly Docket No. 00P-0586)  
Cheeses and Related Cheese Products;  
Proposal to Permit the Use of Ultrafiltered Milk,  
70 Fed. Reg. 60751 (10/19/05) ("Cheese Proposal")

Dear Sir/Madam:

Daisy Brand, Inc. ("Daisy Brand") appreciates the opportunity to submit these comments to the Food and Drug Administration ("FDA") in response to FDA's proposal to amend its regulations to provide for the use of fluid ultrafiltered milk ("UF") in the manufacture of standardized cheeses and related cheese products.

Daisy Brand is a family owned and operated company based in Garland, Texas, which has, since 1917, produced high quality sour cream products. As a technologically advanced company, Daisy Brand continuously explores the use of new processes to improve efficiencies and to make better functioning and more nutritious products. Daisy Brand would like to make three points in response to the Cheese Proposal.

First, Daisy Brand supports FDA's proposal insofar as it recognizes that ultrafiltration is an acceptable process in the dairy industry. Daisy Brand believes that filtration technologies have been unnecessarily restricted in the dairy industry and, as a company, has worked to gain acceptability of these technologies to further advancements in food production and, particularly, in the development of healthy products. Daisy Brand, therefore, applauds FDA's formal acknowledgement that ultrafiltration is a manufacturing technique that should be embraced and that it should be allowed in the manufacture of most standardized cheeses.

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Second, Daisy Brand believes that FDA, in the past, has been inconsistent with respect to its approach to the labeling of ingredients that undergo filtration. Thus, Daisy Brand was extremely pleased to see that in the Preamble to the Cheese Proposal, FDA confirmed that the alternate make procedure provisions of the existing cheese standards allow the use of milk filtration during cheese manufacturing in certain circumstances:

Therefore, the alternate make provision of current cheese standards allows manufacturers to appropriately process the basic ingredient milk during the cheese-making process. For example, the ingredient milk may undergo an additional step of ultrafiltration prior to being introduced into the cheese vat in a single within-batch and within-plant production line for cheese making. In such a process, the ingredient that is introduced in the cheese-making process is milk. However, fluid UF milk purchased or brought in from another plant, even within the same company, that is then introduced into cheese making is considered an alternate ingredient because the ultrafiltration process is used solely for the production of an ingredient that is subsequently used in cheese making. Therefore, in this case, the ingredient is fluid UF milk, not milk. 70 Fed. Reg. at 60754-75

In this paragraph, FDA formally recognizes the critical distinction between the two ways in which ultrafiltration is used to process milk in the manufacture of foods: (1) the use of an ultrafiltration process as part of a single, integrated ("within-batch and within-plant") manufacturing process for a finished product; and, (2) the use of an ingredient that has been subjected to a filtration process and is available commercially either in a powder or liquid form, and thereafter is separately "introduced into" the manufacturing process of a wholly different finished product. FDA recognizes this makes a difference.

Although Daisy Brand believes that requiring manufacturers of products using ultrafiltered milk under the second scenario outlined above to disclose use of ultrafiltration in food labeling by identifying the ingredient as "ultrafiltered milk" may be appropriate, we agree with FDA that such disclosure is not necessary for products in which ultrafiltration is used as part of an integral "within-batch and within plant" manufacturing process. Daisy Brand also believes that this distinction should be applied across all categories of foods in which ultrafiltration, and other filtration technologies, as discussed below, are used.

Finally, Daisy Brand believes that the definitions proposed by FDA do not properly cover all degrees of filtration technology available to the dairy industry, and are inconsistent in terms of the ultimate goal. There is no reason that the filtration

technologies discussed in the preamble other than ultrafiltration should be excluded from these provisions, provided the finished product has the physical, chemical and functional properties required of the standardized term. This is consistent with FDA's own pronouncements on this issue for the past decade:

FDA believes that the food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved. 70 Fed. Reg. at 60756.

*and*

FDA believes that manufactures of standardized foods should have the ability to make use of advances in food technology, provided the basic nature of the food remains the same. 60 Fed. Reg. 67492, 67499 (Dec. 29, 1995)

In contrast to its own stated goals here and earlier with respect to standards of identity in general, FDA is now doing exactly the opposite by proposing overly restrictive language. FDA recognizes that various filtration technologies are acceptable in the cheese industry, and that the critical issue is tied to the finished product. Rather than adopt a rule that embraces these findings, it proposes one that is confining. FDA should meet its stated aim – “flexibility” – by broadening 21 C.F.R. §133.3(a), (b), (f) and (g) to encompass all filtration steps, provided the finished product meets the “essential characteristics of the food”.

Daisy Brand welcomes the benefits that technology, research and innovation bring to product functionality, consumer value, the dairy industry and our society. Regulations that facilitate investment in research and the resulting innovations that create investment in new facilities, processes and technologies benefit our milk producers, processors, their ultimate customers and the larger society we all serve.

Daisy Brand values the opportunity to submit these comments. Daisy Brand appreciates FDA's proposal to allow the use of ultrafiltration in standardized cheeses and related cheese products, and recommends that FDA adopt the suggestions set forth by Daisy Brand above.

Respectfully submitted,

*Diane C. McEnroe* PVL

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