Ref. 5

JACOBY
DAIRY PRODUCT MERCHANTS

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Ms. Elizabeth J. Campbell
United States Food & Drug Administration
Office of Food Labeling
200 'C' Street, S.W.
Washington, D.C. 20204

Dear Ms. Campbell,

Thank you for your time on the phone Friday with Mike McCloskey and myself. We appreciate you willingness to work with us to move this project forward. We hope to reduce costs to the Dairy Industry with this technology, much of which should result in savings to consumers.

We are referred to you by Mr. Joe Smucker, Chief of FDA's Milk Safety Branch, where the issues involving food safety and a HACCP program are being finalized. Subject to a successful conclusion on these issues, we are authorized to commence a pilot sale to Bongards Creamery, Bongards, MN, a manufacturer of Cheddar cheese, most of which is used in their own process cheese plant. To protect Bongards, we need to make sure that we have a clear understanding with regard to labeling matters.

There are two questions to be considered. The first is whether or not it is necessary to label the milk after it has passed through the Ultra filtration system. The second is the question of labeling the cheese that is made from this ultra filtered milk. Let me begin by describing how the system works.

Raw milk is pumped thru a pipe, which is divided into two parts by a membrane. On one side of the membrane passes water, lactose, and small amounts of ash. This is called the Permeate. On the other side of the membrane is the protein, fat, the remainder of the lactose and water. This is called the retentate. Depending on the efficiency of the process, we can concentrate the protein, and fat to 3X, while concentrating the lactose only 1.2X. Each branch of the pipe leads to a separate tank. In our case, we want to ship the retentate to Bongards and keep the permeate on the farm in New Mexico for cattle feed. By doing so we cut our hauling costs by a factor of 3, in addition to delivering a superior product to the customer for cheesemaking.

Enclosed is an analysis of the retentate at various concentrations.

When the retentate gets to Bongards, it would be blended with the raw milk supply at Bongards to achieve a specific solids target for cheese making. Where milk is usually 12%+/-, the retentate would be used instead of Nonfat Dry Milk, or Cream, or both, which are currently being produced at remote locations and hauled to cheese plants to be used by cheesemakers to increase the solids content and, therefore, the efficiency of their process. These fortifiers are currently described under the 'Alternate Make Procedure'.

The retentate makes far superior cheese, of a more consistent nature, identical to the cheese made from non fortified milk. There is no comparison to the consistency of the cheese made from the retentate and to the cheese after fortifying with the products used under the 'alternate make procedure'.

In fact, retentate is used currently by some cheese processors for this reason. The only difference is that most processors use the ultra filtration method in house to set the ideal solids for their particular style of cheese. We intend to do the ultra filtration on the farm, thus saving the haul from the farm to the market. This hauling does not change the composition of the ultra filtered milk.

There are those who say that since some lactose is removed, that what we would be shipping to Bongards is not milk. This is a 'red herring'. The cheese made from this retentate does not vary from that made from untreated milk. What varies is the whey, which is a byproduct containing lactose with normally wide swings in composition, depending on the cheese from which it is made.

In our opinion, the issue of labeling rest on whether the cheese differs in any material way from cheese made only from unfortified fresh milk. It does not, and if necessary, we would be willing to prove this in the pilot movement. But since Bongards is a USDA facility, they need to have USDA approval to be able to run the pilot project. USDA defers to FDA on the issues of standards of identity. Bongards makes process cheese, and they have many labels, all of which would have to be changed if they are required to label. The costs associated with this labeling would be prohibitive.

Our first choice would be not to have to worry about labeling at all. This product is milk. This technology is currently in use with no labeling in the cheese industry and represents an improvement over all the existing products used under the 'alternate make procedure'.

Our second choice would be to name the ultra filtered milk, but not have to label the end cheese product. Should FDA not be comfortable with this option, we would be happy to run a testing program at Bongards during the pilot period to show that the composition of the end products is the same with fresh milk and ultra filtered fresh milk. We would welcome working with your department to design protocols, and would be willing to bring in respected academics, who meet with your approval, to run the program. But, to do this, it is necessary that Bongards not have to label their finished product during this pilot period.

When we are finished, we want to sell this milk, using this methodology, to all segments of the cheese industry in both the United States and Mexico. We can be competitive in Mexico City and in Minneapolis from California and New Mexico. From a practical standpoint, there is no reason why we should be hauling Nonfat dry milk and cream for use in the cheese industry when this methodology is available.

This is a confidential project and we would appreciate your discussing this only with either Mike McCloskey, Jerry Kozak, of IDFA; Dave Hibbard of Membrane Systems, or myself outside of your department.

We will be ready to go by June 1st and would appreciate your response so that we can move forward without delay.

Sincerely yours,

Ted Jacoby!

Ted Jacoby, Jr.

cc: Mr. Joe Smucker.Mr. Mike McCloskey
Mr. David Hibbard.Mr. Jerry Kozak