

## **American Dairy Products Institute**

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December 2, 1999

Dockets Management Branch Food and Drug Administration Department of Health and Human Services Room 1-23 12420 Parklawn Drive Rockville, Maryland 20857

Dear Sirs or Mesdames:

Enclosed are four (4) copies of the American Dairy Products Institute's Citizen Petition Requesting Amendment to Definition of "Milk" In C.F.R. Part 133.3.

Please contact the undersigned if further information is needed. Thank you.

Sincerely yours,

Warren S. Clark, Jr., Ph.D

Chief Executive Officer

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WARREN S. CLARK, JR., PH.D. Chief Executive Officer

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> Re: Citizen Petition Requesting Amendment to Definition of "Milk" In 21 C.F.R. Part 133.3

Dear Sirs or Mesdames:

Pursuant to Section 401 of the Federal Food, Drug, and Cosmetic Act, the American Dairy Products Institute (ADPI) hereby requests that the Food and Drug Administration amend the definition of "Milk," as provided in 21 C.F.R. § 133.3(a), to include fluid ultrafiltered (UF) milk. The requested amendment will improve efficiencies in cheese manufacturing, and be consistent with honesty and fair dealing in the interest of consumers.

ADPI is the trade association of the nation's leading manufacturers and processors of processed dairy products. Many of ADPI's members, including the members of its Cheese Division, are manufacturers of cheeses and cheese products governed by FDA standards of identity, as set forth in Part 133 of Title 21 of the Code of Federal Regulations, and, accordingly, have a strong interest in the permitted utilization of technological developments that potentially increase efficiencies in the production of cheese. The Institute also is an active party in the development/modification of international cheese standards.

### A. ACTION REQUESTED

ADPI requests that the definition of "Milk," as set forth in 21 C.F.R. § 133.3(a) be amended as follows (underlined provisions to be added):

Milk means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, reconstituted milk, and dry whole milk. Water in a sufficient quantity to reconstitute concentrated and dry forms, may be added. Milk may be subjected to an ultrafiltration process that results in a fluid ultrafiltered (UF) milk for use in the manufacture of cheese.

### B. STATEMENT OF GROUNDS

Fluid UF milk is derived by the partial removal of water and lactose from fresh fluid milk. It is a technological advancement of the traditional clarification and concentration processes that already are permitted under the existing cheese standards. The permitted use of fluid UF milk in the manufacture of cheese would assist in the more efficient movement of milk from areas of the country with an excess of fluid milk to those areas with an insufficient supply. These increased efficiencies will result in benefits to consumers without alteration of cheese composition, characteristics, or flavor that they have come to expect in the cheeses governed by the standards.

## C. ENVIRONMENTAL IMPACT

The requested action is exempt from the requirement to provide an environmental impact assessment pursuant to 21 C.F.R. § 25.32(a).

### D. CERTIFICATION

ADPI certifies that, to the best of its knowledge and belief, this petition includes all information and views on which it is based, and that it is not aware of any data or information unfavorable to the petition.

Respectfully submitted,

Warren S. Clark, Jr., Ph.D.

Chief Executive Officer