DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 29, 2007

Philip Carroll
Head, Milk Policy Division,
Department of Agriculture, Fisheries and Food
Kildare St., Dublin 2

Dear Mr. Carroll:

It is with great pleasure that I express to you the intention of the United States Food and Drug Administration, Department of Health and Human Services (FDA) to cooperate with the Department of Agriculture and Food of Ireland (DAF) concerning certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States.

The mutual goals of FDA and DAF in establishing certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States is to assure that contaminated products will not be imported into the U.S. and to minimize the need for extensive FDA audit sampling of these products from Ireland. FDA and DAF have a history of cooperation on this issue and it is, therefore, desirable that the two agencies continue to cooperate to maintain and improve consumer protection.

DAF intends to ensure that caseins, caseinates, and mixtures thereof that are intended for export to the United States are fit for human consumption in that they comply with the requirements of the Federal Food, Drug, and Cosmetic Act of the United States and the Public Health Service Act of the United States. DAF will inspect and analyze samples of these caseins, caseinates, and mixtures thereof to ensure that they comply with these requirements.

To discharge its responsibilities regarding caseins, caseinates, and mixtures thereof, DAF intends to:

1. Inspect and analyze each lot[1] of caseins, caseinates, and mixtures thereof produced in Ireland for export to the United States to assure that it is Salmonella-negative[2] and phosphatase-negative[3].

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[1] LOT: A lot is a quantity of casein, caseinates, or mixtures thereof packaged by one manufacturer during a definite period of time not exceeding one (1) day. The manufacturing process, including milling and packaging, is performed by using a perfectly identified processing line. Caseins, caseinates, or mixtures thereof intended for export to the United States are packaged, after milling, in identical containers identified by a unique code or mark traceable to the manufacturer.

[2] SALMONELLA-NEGATIVE: The absence of *Salmonella* in thirty (30)

2. Require that all containers of a lot of caseins, caseinates, and mixtures thereof that are to be exported to the United States be certified as complying with the provisions of this letter and all other requirements of the Federal Food, Drug, and Cosmetic Act of the United States and its implementing regulations and be identified by a lot number.

3. Require that all of the information that is required by the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act of the United States be included on the label and labeling of individual products.

4. Furnish FDA, upon request, with a full description of the manufacturing processes and quality controls used to ensure that the caseins, caseinates, and mixtures thereof that are produced are fit for human consumption.

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes of the United States. FDA directs its activities toward the protection of the public health in the United States by ensuring that foods are safe and wholesome and are honestly and informatively labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to ensure compliance with these statutes. FDA makes a concerted effort to ensure that foods entering the United States meet the same standards as domestic products.

To discharge these responsibilities regarding caseins, caseinates, and mixtures thereof, FDA intends to:

1. Audit samples of caseins, caseinates, and mixtures thereof certified by DAF to ensure that the products exported from Ireland and offered for import into the United States comply with the requirements of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Public Health Service Act, and other related statutes of the United States.

2. Share any information obtained through its audit sampling with DAF and the

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subsamples, each of twenty-five (25) grams, that have been taken from bags in the same lot of product immediately before closing and tested using the procedures contained in the current edition of the "Bacteriological Analytical Manual." The Bacteriological Analytical Manual can be accessed at http://www.cfsan.fda.gov/~ebam/bam-toc.html.

[3] PHOSPHATASE-NEGATIVE: The absence of phosphatase activity in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from bags in the same lot of product immediately before closing and tested using the method contained in the current edition of the "Official Methods of Analysis." This method may be obtained from the AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877 USA, telephone 301-924-7077, fax 301-924-7089, www.aoac.org.

First Secretary of the Embassy of Ireland in Washington.

3. Promptly notify DAF and the First Secretary of the Embassy of Ireland in Washington of the detention of any caseins, caseinates, and mixtures thereof.

4. Share expertise and provide consultative assistance to DAF when necessary to assure the safety of the caseins, caseinates, and mixtures thereof exported to the United States.

This letter is not intended to create obligations under international or other law, and all cooperation is subject to the availability of appropriated funds, personnel, and other resources. FDA and DAF each intend to bear their own expenses associated with this cooperation. Either FDA or DAF may terminate this cooperation on 30 days written notice to the other. The cooperation will continue for a period of five years and may be extended for additional five-year periods upon consent of FDA and DAF.

I look forward to beginning this cooperation upon receipt of your affirmative reply.

Sincerely,

Murray M. Lumpkin, M.D., M.Sc.
Deputy Commissioner
International and Special Programs
United States Food and Drug Administration