

**SUBJECT:**

## MEMORANDUM OF UNDERSTANDING

Exporting Dry Milk  
Products to the  
United States

(FDA Agreement  
Number 225-76-  
2000)

(Previously CPG  
7156e.01)

**Notes:**

The FDA contact  
for this MOU is  
Frank MacKeith,  
HFS-585

Tel No.  
202-205-4045

This MOU is in  
effect indefinitely.

See: BAM, 8th  
Ed., 1995 or  
AOAC Methods of  
Analysis, 16th Ed.,  
1995

Between The

MINISTRY OF AGRICULTURE AND FISHERIES  
NEW ZEALAND

And The

FOOD AND DRUG ADMINISTRATION

**PURPOSE:**

It is the aim of the parties to this Memorandum of Understanding to facilitate and simplify the importation of dry milk products into the United States of America; to improve compliance with specifications of the Food and Drug Administration (FDA); to minimize, and in the future, diminish the risk of products being returned because of failure to comply with specifications; and eventually, to reduce the time-consuming practice of lot by lot examination by the receiving country.

For purposes of this Memorandum, both parties agree to the definitions following:

**Dry Milk Products:** Dry milk products include nonfat dry milk, whole milk powder, dried whey, buttermilk powder, casein, and caseinates.

**Lot:** A quantity of dry milk product produced during a discrete period of time, not exceeding 1 day, by the manufacturer, in one continuous process using a single processing line, packaged in identical containers identified by a code or mark traceable to the manufacturer.

**Salmonella negative:** The absence of Salmonella in 30/25 subdivisions, each taken from a lot of dry milk product when tested by procedures outlined in the Bacteriological Analytical Manual for Foods and the AOAC Methods, 12th ed.

**Phosphatase negative:** No indication of underpasteurization or contamination with raw milk when tested by one of the methods in AOAC Methods, 12th ed., section 16.101, et seq.

**Penicillin negative:** No detectable residue of penicillin when tested by the cylinder method of Kramer, et al., 1968.

MINISTRY OF AGRICULTURE AND FISHERIES, NEW ZEALAND

1. The Ministry of Agriculture and Fisheries, New Zealand agrees to inspect each lot of dry milk product produced in New Zealand and offered for export to the United States of America to assure that the lot is Salmonella negative, phosphatase negative, and penicillin negative.

## Notes:

2. The Ministry of Agriculture and Fisheries, New Zealand agrees to issue an export certificate for only those lots which meet such criteria of paragraph 1. above. Any lot which fails to meet such criteria will be denied export to the United States of America.
3. The Ministry of Agriculture and Fisheries, New Zealand agrees to require all containers of all lots exported to the United States of America to be identified by lot number together with all other information required by the Federal Food, Drug, and Cosmetic Act.
4. The Ministry of Agriculture and Fisheries, New Zealand agrees to include in the certificate for each lot exported to the United States of America the following information:
  - A. Lot identification, including name and address of manufacturer;
  - B. Number and size of containers in the lot;
  - C. Analytical results for Salmonella, phosphatase, and penicillin;
  - D. Date of the certificate; and
  - E. Name and stamp, or seal of authorizing official.

The valid certificate will accompany the shipping manifest.
5. The Ministry of Agriculture and Fisheries, New Zealand agrees to furnish to the Food and Drug Administration a copy of the regulations, and procedures used to assure that dry milk products are sanitary.
6. The Ministry of Agriculture and Fisheries, New Zealand agrees to furnish to the Food and Drug Administration a full description of the manufacturing processes and quality controls used to assure the production of sanitary dry milk products.

## UNITED STATES OF AMERICA

In fulfillment of its responsibilities, the Food and Drug Administration is responsible for the safety and quality of dry milk products imported into this country for human consumption:

1. The Food and Drug Administration will sample products certificated under this program to assure that the exporting country and the exported products comply with specifications set forth in this agreement, and all other requirements of the Federal Food, Drug, and Cosmetic Act. The intensity of sampling may be

Notes:

reduced on gaining confidence in the compliance of the products to these specifications.

- 2. The Food and Drug Administration will share information about its audit sampling with the Ministry of Agriculture and Fisheries, New Zealand.
- 3. The Food and Drug Administration will share expertise and will provide consultative assistance to the exporting country when necessary to assure the safety of the dry milk products exported to the United States of America.

METHODOLOGY REFERENCES

The following methods are those to which reference has been made in the Memorandum:

A. Bacteriological Analytical Manual, 8th Edition, 1995

FDA, Center for Food Safety and Applied Nutrition, 200 C St., S.W., Washington, D.C. 20204

B. Official Methods of Analysis - AOAC 16th Edition, 1995 481 N. Frederick, Ave., Suite 500 Gaithersburg, MD 20877-2417

- A. Food and Drug Administration, Bureau of Foods, Division of Microbiology. Bacteriological Analytical Manual for Foods, 3rd ed., Washington, DC 20044, 1972.
- B. "Official Methods of Analysis," Association of Official Analytical Chemists, 12th ed., Box 540, Benjamin Franklin Station, Washington, DC 20044, 1975
- C. Kramer, J., G.G. Carter, B. Arret, J. Wilner, W.W. Wright, and A. Kirshbaum. Antibiotic residues in milk, dairy products, and animal tissues, National Center for Antibiotic and Insulin Analysis, Food and Drug Administration, Washington, D.C. 20204, 1968.

The Ministry of Agriculture and Fisheries, New Zealand, and the Food and Drug Administration, United States of America, agree that this Memorandum shall become effective on the date it is signed by both parties. It shall remain in effect, and govern all dry milk products exported to the United States of America, pending revision or revocation at the request of either agency. Upon the effective date, this Memorandum of Understanding will be published in the FEDERAL REGISTER. A copy of the Memorandum will be available for public review at the office of the Hearing Clerk, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

In witness whereof, the agencies have executed this Memorandum.

FOR THE MINISTRY OF AGRICULTURE AND FISHERIES, NEW ZEALAND:

FOR THE FOOD AND DRUG ADMINISTRATION, UNITED STATES:

BY: \_\_\_\_\_/s/\_\_\_\_\_

BY: \_\_\_\_\_/s/\_\_\_\_\_

TITLE: Director, General

TITLE:

DATE:

DATE: November 11, 1975

