SUBJECT:

Dry Milk Products

(FDA Agreement Number 225-80-8000)

(Previously CPG 7156f.01)

Notes:

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

Tel. No. 202-205-4045

This MOU is in effect indefinitely.

US Dept. of Health Educ. & Welfare is now Dept. of Health and Human Services

MEMORANDUM OF UNDERSTANDING

Between The

DEPARTMENT OF PRIMARY INDUSTRY, AUSTRALIA

And The

U.S. DEPARTMENT OF HEALTH, EDUCATION & WELFARE
FOOD AND DRUG ADMINISTRATION

I. OBJECTIVES

The goals of the Food and Drug Administration (FDA) and the Australian Department of Primary Industry (DPI) in entering into this Memorandum of Understanding (MOU) are to:

A. Expedite the entry of Australian dry milk products at U.S. ports by minimizing the need for extensive FDA sampling of DPI certified dry milk products from Australia.

B. Give assurance that Australian dry milk products exported to the U.S. are free from contamination or under processing in accordance with the standards set out in this MOU.

II. DEFINITIONS

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

DRY MILK PRODUCTS: Dry milk products include dry whole milk, nonfat dry milk, low fat dry milk, dry cream, dry whey, dry buttermilk, casein; caseinates and co-precipitates. Products marked "FOR NON-EDIBLE USE ONLY" are excluded from this definition.

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

PENICILLIN NEGATIVE: The lot of dry milk product is penicillin negative when the samples from that lot, taken in accordance with Section IV "SAMPLING" of this MOU, or units composited from those samples in accordance with that section, are reported as penicillin G not detectable, when tested by one of the methods described in Attachment A, "ANALYTICAL METHODS."

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PHOSPHATASE NEGATIVE: The lot of dry milk product is phosphatase negative when the samples from that lot, taken in accordance with Section IV "SAMPLING" of this MOU, or units composited from those samples in accordance with that section, are reported as phosphatase not detectable when tested by one of the methods described in Attachment A, "ANALYTICAL METHODS".

SALMONELLA NEGATIVE: The lot of dry milk product is Salmonella negative when the samples from that lot taken in accordance with Section IV "Sampling" of this MOU, or units composited from those samples in accordance with that section, are reported as Salmonella not detectable, when tested by one of the methods described in Attachment A, "ANALYTICAL METHODS".

III. OBLIGATIONS OF PARTICIPANTS

A. DEPARTMENT OF PRIMARY INDUSTRY, AUSTRALIA

The Department of Primary Industry (DPI) is responsible to the Government of the Commonwealth of Australia for the administration of the Exports (Dairy Produce) Regulations. In fulfilling its responsibilities under those Regulations, DPI directs its activities towards the reputation of the dairy exports from the Commonwealth of Australia by ensuring that dairy foods are safe and wholesome and that such products are honestly and informatively labeled. This is accomplished by inspecting the processed products before distribution and by collecting and examining samples to assure compliance with these Regulations. To carry out these responsibilities as they relate to exports of dry milk products and in fulfillment of commitments under this Memorandum of Understanding:

1. The Department of Primary Industry has furnished the Food and Drug Administration with copies of the current regulations and procedures used to assure that dry milk products are sanitary. The DPI will supply the FDA with copies of any future changes as they become effective.

2. The Department of Primary Industry has informed FDA of the sampling and testing procedures involved in the microbiological/chemical testing of dry milk products manufactured in export establishments in Australia registered under the Exports (Dairy Produce) Regulations as these procedures operated on and from January I, 1978. DPI will inform the FDA of any modifications initiated in the Australian analytical regime.

3. The Department of Primary Industry will furnish to the Food and Drug Administration, on request, a full description of the manufacturing process and quality controls used in respect to

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any particular lot to assure that the production of the dry milk product concerned is sanitary.

4. The Department of Primary Industry will inspect each lot of dry milk product produced in Australia and offered for certification and exportation to the United States of America to assure that the lot is penicillin negative, phosphatase negative, and Salmonella negative.

5. The Department of Primary Industry will issue a separate certificate for only those lots which meet the criteria in 4 above. Any lot offered for certification which fails to meet such criteria shall be denied export to the United States of America.

6. The Department of Primary Industry will require all packages in each lot exported to the United States of America to be identified by a lot number.

7. The Department of Primary Industry will 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. Name and size of containers in the lot;
   c. Information that the product described is negative for penicillin, phosphatase and Salmonella in accordance with the requirements of this MOU;
   d. Date of the certificate; and,
   e. Name and stamp, or seal of authorizing official.

The validated certificate will accompany the shipping manifest.

B. Dept. of Health, Educ. & Welfare is now Dept. of Health and Human Services

B. THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare is charged by the Government of the United States of America with the enforcement of the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. In fulfilling its responsibilities under the Acts, FDA directs its activities toward the protection of the public health of the United States of America by ensuring that foods are safe and wholesome and that products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and by collecting and examining samples to assure compliance with these Acts. To carry out these responsibilities as they relate to imported dry milk products and in

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fulfillment of its Memorandum of Understanding commitment:

1. The Food and Drug Administration acknowledges that the Department of Primary Industry has informed FDA of the sampling and testing procedures involved in the microbiological testing of dry milk products manufactured in export establishments in Australia registered under the Exports (Dairy Produce) Regulations as these procedures operate on and from January 1, 1978.

2. The Food and Drug Administration will sample dry milk products certified under this Memorandum of Understanding to assure that the exporting country and the exported products comply with specifications set forth in this Memorandum. On commencement of this MOU, the intensity of sampling of lots of DMP from Australia, will not exceed the highest rate of lot sampling applied to any other country entering into an MOU. The intensity of sampling may be reduced on gaining confidence in the compliance of the products to these specifications. The FDA may also check for other attributes to make sure the products also comply with the other requirements of the Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act.

3. The Food and Drug Administration will share any information obtained through its audit sampling with the Department of Primary Industry through the Australian Embassy.

4. The Food and Drug Administration will promptly notify the Australian Embassy of any detention of dry milk products covered by the Memorandum and of any modifications in the Acts or the regulations which pertain to the dry milk products.

5. 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.

IV. SAMPLING

Subsamples will be collected as follows:

Using aseptic sampling techniques, 30 subsamples, each containing approximately 100 grams, will be randomly collected from each lot. If the lot contains packaged units weighing approximately 225 grams (about 8 ounces) or less, but more than 100 grams, 30 of these units will be randomly collected unopened, from the lot.

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V. ANALYTICAL METHODOLOGY

The methodology used in analyzing samples collected for the purpose of this MOU shall be acceptable to both the U.S. Food and Drug Administration and the Australian Department of Primary Industry. The analytical methods currently in use are listed in Attachment A.

VI. ADMINISTRATIVE PROCEDURES

A. Activation of MOU

This Memorandum of Understanding will become effective 60 days after signature by the parties and will remain in effect pending revocation by either party.

B. Modification of MOU

Changes in this Memorandum of Understanding may be proposed by either of the parties. When the proposed changes are acceptable to both parties, they will be incorporated into the Memorandum.

C. Termination of MOU

This Memorandum of Understanding may be revoked by eitherparty. The Memorandum of Understanding will cease to operate 60 days after Notice of Intent to Revoke has been given by one party to the other.

The terms of the Memorandum of Understanding would continue to apply in respect to dry milk products manufactured prior to the date of the Notice of Intent to Revoke.

D. Publication of MOU

Upon its effective date, the Memorandum of Understanding will be published in the Federal Register. A copy will be available for public review at the Office of the Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Maryland, 20857.

Notes:

In witness whereof, the agencies have executed this Memorandum of Understanding covering dry milk products.

For the Department of Primary Industry

BY: /s/

The Minister (Commercial) is currently Mr. Steve Deady

TITLE: Minister (Commercial), Embassy of Australia

COUNTRY: Australia

DATE: November 28, 1979

For the Food and Drug Administration

BY: Joseph P. Hile /s/

TITLE: Associate Commissioner for Regulatory Affairs

The ACRA is currently Mr. Ronald G. Chesemore

COUNTRY: United States of America

DATE: November 23, 1979

Notes:

ATTACHMENT A

Analytical Methods

The subsamples of dry milk products will be aseptically reconstituted. The 25 gram portions taken from each of the 30 subsamples collected from a lot of dry milk product may be composited up to an amount of 400 grams in each composite. The composites or individual 25 gram portions shall be reconstituted in an amount of diluent at least eight and no more than ten times the weight of the product.

A. Penicillin

Reconstituted dry milk products will be tested for penicillin residues by either of the following methods:

1. See: Methods of Analysis - AOAC, 16th Ed., 1995

1. The S. lutea, cylinder method as described in Methods of Analysis - AOAC, Twelfth Edition, Section 42.252 et. seq., p. 812-813; changes in Official Methods of Analysis made by the Nineteenth Annual Meeting, Oct. 18-21, 1976/Third Supplement to 12th Edition, Journal of AOAC, Volume 60, March 77, pp. 484-485, Section 42(4).

2. The B. stearothermophilus, variety calidolactis, disk assay method described in the Australian Standard Method of Microbiological Examination of Dairy Products and for Dairy Purposes, AS 1095.1.3, clause 3.3.2.

While the Department of Primary Industry may choose to use either of these methods for certification of lots, FDA will continue to use the S. lutea cylinder method in its regulatory enforcement to assure that imported dry milk products are free of detectable penicillin residues.

B. Phosphatase

Reconstituted dry milk products will be tested for phosphatase activity by either of the following methods:

1. Scharer Rapid Method for Phosphatase Analysis, described in Standard Methods for the Examination of Dairy Products, Fourteenth Edition, 17-8, Section 18.4; or,

2. Aschaffenberg and Mullen Method, described in the Australian Standard Method of Microbiological Examination of Dairy Products and for Dairy Purposes. AS 1095.1.3, clause 3.2.6.

C. Salmonella

Reconstituted dry milk products will be analyzed for presence of Salmonella according to either of the methods contained in:

Notes:

1. See: Bacteriological Analytical Manual , 8th Ed., 1995

2. See: Methods of Analysis, AOAC, 16th Ed., 1995

1. Bacteriological Analytical Manual, Fifth Edition, 1978, Chapter VI - Isolation and Identification of Salmonella.

And

2. Methods of Analysis - AOAC, Twelfth Edition, 1975, Chapter 46, Microbiological Methods, Section 46.013, et. seq. (Note: Both (A) and (B) give methods based upon 100 gram samples. For this MOU, 30/25 gram samples will be used.); or,

3. Standards Association of Australia viz AS 1095.3.8 (1976) Methods of Microbiological Examination of Dairy Products and for Dairy Purposes.

ATTACHMENT B

References of Analytical Methods Cited in this MOU:

1. Australian Standard, AS 1095 (1976): Methods of Microbiological Examination of Dairy Products and for Dairy Purposes, Standards Association of Australia, Standards House, 80 Arthur Street, North Sydney, N.S.W. Australia.

2. See: BAM, 8th Ed., 1995 AOAC: 481 N. Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417 Tel. No. 301-924-7077

2. Bacteriological Analytical Manual, Fifth Edition, 1978. The Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

3. See: Methods of Analysis, AOAC, 16th Ed., 1995 See AOAC current address above.

3. Methods of Analysis - AOAC, Twelfth Edition, 1975. Changes in Official Methods of Analysis made at the Nineteenth Annual Meeting, Oct. 18 - 21, 1976/Third Supplement to 12th Edition, Journal AOAC, Volume 60, March 77, pp. 484 - 485, Section 42(4). The Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C., 20044.

4. See: Standard Methods for the Examination of Dairy Products, 16th Ed., 1993 American Public Health Assoc., P.O. Box 743 Waldorf, MD 20604

4. Standard Methods for the Examination of Dairy Products, Fourteenth Edition, 1978, Section 18.4. American Public Health Association, 1015 Eighteenth Street, N.W., Washington, D.C. 20036.

In witness whereof, the Agencies have executed this Memorandum of Understanding covering dry milk products.