Board of Governors of the Federal Reserve System, July 22, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–19190 Filed 7–27–99; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Nutritional Biochemistry Cooperative Agreements for Innovative Technology Development Grant for Detection and Monitoring of Diabetic Hypoglycemia by Non- or Minimally-Invasive Techniques

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Nutritional Biochemistry Cooperative Agreements for Innovative Technology Development Grant for Detection and Monitoring of Diabetic Hypoglycemia by Non-or Minimally-Invasive Techniques, Program Announcement #99151.

Times and Dates: 8:30 a.m.–9 a.m., August 12, 1999 (Open); 9 a.m.–5 p.m., August 12, 1999 (Closed); 9 a.m.–4 p.m., August 13, 1999 (Closed).

Place: Atlanta Marriott North Central, 2000 Century Boulevard NE, Atlanta, Ga. 30345–3377. Telephone 404/325–0000.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #99151.

Contact Person for More Information: Dayton T. Miller, Ph.D., Chief, Nutritional Biochemistry Branch, NCEH, CDC, 4770 Buford Hwy., m/s F18, Atlanta, Ga. 30341–3724. Telephone 770/488–4579, e-mail dtm1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 22, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–19235 Filed 7–27–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–8000]

Memorandum of Understanding Between the Food and Drug Administration and People's Republic of China

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and People's Republic of China. The purpose of the MOU is to establish a certification system that will increase the likelihood that daily-use ceramicware manufactured in the People's Republic of China and offered for import into the United States will comply with U.S. law.

DATES: The agreement became effective May 20, 1999.

FOR FURTHER INFORMATION CONTACT: Frank M. MacKeith, Center for Food Safety and Applied Nutrition (HFS–585), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4045.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 20, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

BILLING CODE 4160–01–F

225-99-8000

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

AND THE

STATE ADMINISTRATION OF ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA

COVERING CERAMICWARE INTENDED FOR USE IN THE PREPARATION, SERVING OR STORAGE OF FOOD OR DRINK AND OFFERED FOR EXPORT TO THE UNITED STATES OF AMERICA

PREAMBLE

The Parties to this Memorandum of Understanding (MOU), the Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America, and the State Administration of Entry-Exit Inspection and Quarantine of the People's Republic of China (SAIQ), hereinafter referred to as the "Parties,"

RECOGNIZING that SAIQ is the government agency in charge of unified supervision and administration of the China's export and import commodity inspections,

RECOGNIZING that the China Import and Export Commodity Inspection Bureaus (CCIB), under the authority of SAIQ, are authorized by SAIQ to conduct the inspections, and collect and examine representative samples of all exports of ceramicware from China to ensure that qualified daily-use ceramicware from SAIQ/CCIB certified factories intended for export to the United States is safe for use in the preparation, serving, or storage of food or drink, and

RECOGNIZING that the Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America is charged with the enforcement of, among other laws, the Federal Food, Drug, and Cosmetic Act, and the Fair Packaging and Labeling Act,

AGREE as follows:

I. PURPOSE

The mutual goals of FDA and SAIQ, in entering into this MOU, are to:

A. Establish a certification system that will increase the likelihood that daily-use ceramicware manufactured in the People's Republic of China and offered for import into the United States will comply with United States law. To that end, this MOU sets forth the Criteria for Certification (the Criteria) of: 1) ceramicware to be exported directly from the People's Republic of China or from the People's Republic of China via Hong Kong to the United States, as indicated by those involved in the trade (ceramicware manufacturers or importers/exporters), and intended for use in the preparation, serving, or storage of food; and 2) firms in the People's Republic of China manufacturing such ceramicware.

B. Enable the FDA to reduce the frequency of its sampling of daily-use ceramicware from factories in the People's Republic of China certified by the China Import and Export Commodity Inspection Bureaus (CCIBs) of SAIQ and offered for import into the United States, in accordance with FDA's confidence in the effectiveness of the SAIQ/CCIB factory certification system.

C. Provide for the cooperative exchange of scientific and regulatory information, technical assistance, and research to help ensure the safety, quality, and proper labeling of ceramicware exported from the People's Republic of China and offered for entry into the United States, under the terms of this MOU.

II. DEFINITIONS

For the purposes of this MOU, both Parties agree to the following definitions:

A. Action Level - means the concentration of an adulterant in or on a commodity at which FDA may take regulatory action against the commodity. The action level is non-discriminatory, applies without distinction to domestic and imported products, and reflects FDA's current thinking on the concentration of the adulterant in or on the commodity at which regulatory action is appropriate.

B. Audit Sample - means a sample collected to verify analytical results provided through a certification system or private laboratory analysis that purports to show that a product complies with the Food, Drug, and Cosmetic Act and/or regulations.

C. Certified Delivery Lot - means a quantity of ceramicware offered for entry into the United States at one time, that is produced by a factory certified by a CCIB, and is in compliance with the CRITERIA FOR CERTIFICATION FOR EXPORT OF CERAMICWARE set forth in Attachment B this MOU (Criteria). A certified delivery lot may consist of one or

more factory lots or production lots. All shipping cartons and retail cartons in the lot are identified by a CCIB sticker/logo that is imprinted with the standardized factory code of the CCIB-certified factory.

D. Daily Use Ceramicware - means ceramic dinnerware intended for use in the preparation, serving, or storage of food or drink that usually are inexpensive, more durable items that have the expectation of being commonly used by the consumer.

E. Detention Without Physical Examination - means FDA's administrative act of detaining an import entry of a specified article without physical examination on the basis of information regarding its past history of violation of the Food, Drug, and Cosmetic Act or other information whereby there is an appearance that the product may be violative.

F. Electronic Entry Processing System - means an automated FDA import entry processing system which allows for a pre-determined percentage of import entries to be cleared by electronic means for entry into commerce in the United States. The pre-determined percentage of such cleared entries, referred to as a "may proceed rate," depends upon, among other things, the demonstrated degree of compliance of the commodity/country/firm combination with the laws enforced by FDA and their implementing regulations, and FDA's level of confidence that the commodity/country/firm combination will comply with such laws and regulations.

G. Factory Code - means an alpha-numeric code consisting of three parts with a total of six characters (five figures and one letter) for a particular plant. The first two figures represent the province or city, followed by the letter "T" for ceramicware, and followed by a set of three figures that SAIQ/CCIB uses to designate the factory number within each province or city.

H. Factory Lot or Production Lot - means a unit of ceramicware that is uniform and that represents ceramicware from no more than one homogeneously milled slip from the same materials. The factory lot or production lot must be uniform in the time and temperature of firing and the composition and application of the decorations and glazes.

I. Factory Lot Number or Production Lot Number - means a number assigned by the factory that relates to both the date and period of manufacture and denotes a distinct group of conditions (manufacturing date, kiln conditions, materials, patterns, etc.) that may affect the quality of the ceramicware.

J. Flatware - means ceramic articles that have an internal depth, as measured from the lowest point to the horizontal plane passing through the upper rim, that does not exceed 25 millimeters.

K. Hollowware - means ceramic articles having an internal depth, as measured from the

lowest point to the horizontal plane passing through the upper rim, greater than 25 millimeters. The two categories of hollowware and their sub-categories are:

1. Large hollowware - Ceramic articles with a capacity of 1.1 liter or more.

   a. Pitchers - Large ceramic hollowware vessels (sometimes known as jugs) commonly used for storage and dispensing of fruit and vegetables juices or other acidic beverages at or below room temperature. Pitchers are generally manufactured without a lid but with a handle and lip spout. Creamers, coffeepots and teapots are not considered to be pitchers. Depending upon capacity, creamers, coffeepots and teapots will be considered small or large hollowware.

   b. Other (not including pitchers) - Ceramic vessels with a capacity of 1.1 liter or more. (Note that different action levels apply to pitchers than to large hollowware other than pitchers under the Criteria.)

2. Small hollowware - Ceramic articles with a capacity of less than 1.1 liter.

   a. Cups and Mugs - Small ceramic hollowware vessels commonly used for consumption of beverages, for example, coffee or tea, at or above room temperature. Cups and mugs usually, but not exclusively, have a capacity of about 240 milliliters (240 mL) or 8 fluid ounces (8 fl. oz.) and are manufactured with a handle. Cups generally have a base and curved sides while a mug has cylindrical sides.

   b. Other (not including cups and mugs) - Ceramic vessels with a capacity of less than 1.1 liter. (Note that different action levels apply to cups and mugs than to small hollowware other than cups and mugs under the Criteria.)

L. May Proceed Rate - means the rate of import entries entered into domestic commerce without FDA physical examination or sampling that varies from a high near 100% for commodity/country/firm combinations for which FDA has a high confidence of compliance (e.g., particular firms have demonstrated a good compliance history and are certified by a foreign government), to a low of 0% for commodity/country/firm combinations for which FDA has a low confidence of compliance (e.g., firms with a history of noncompliance with the Food, Drug, and Cosmetic Act).

M. Sample - means portion of a certified delivery lot being offered for entry into the United States that is intended to be representative of that lot. It will consist of a number of units or subsamples, collected as specified in Article V, governing SAMPLE COLLECTION.

N. Shipping Carton - means a box that contains one or more retail cartons of daily-use

ceramicware produced by a CCIB-certified factory, has the CCIB sticker/logo with the CCIB factory code imprinted on it, and has the factory name and code, the year of production of the factory lot and the factory lot number printed on its exterior surface.

O. Traditional Ceramicware - means the ceramic dinnerware, spoons and other ware that might be used to contain or store foods and beverages. Such items are usually porcelain items, hand-painted with soft lead-containing enamels, and highly decorated with vivid colors and intricate patterns, which have been found to leach unacceptable levels of lead. The patterns are of red, yellow, and green, and referred to as "Longevity," "Flowers on Black," and "One Thousand Flowers," for example.

III. BASIC OBLIGATIONS

A. THE STATE ADMINISTRATION OF ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA

SAIQ shall ensure that daily-use ceramicware products that are intended for export to the United States comply with the provisions of this MOU. SAIQ agrees to direct the CCIBs to inspect and certify factories, and inspect and analyze samples, to ensure that ceramicware intended to be exported to the United States complies with these requirements and provisions.

To carry out its responsibilities, SAIQ agrees to:

1. Implement and oversee a daily-use ceramicware factory certification system;

2. a. Provide, on a continuing basis, FDA's Center for Food Safety and Applied Nutrition with a nationally standardized listing of factory names, addresses and codes of CCIB-certified daily-use ceramicware factories that export such daily-use ceramicware to the United States;

   b. Authorize the export of qualified daily-use ceramicware to the United States only from CCIB-certified factories;

3. a. Affix to each shipping carton and retail carton containing daily-use ceramicware that meets the Criteria a CCIB "H" (for Health) sticker/logo that is imprinted with the factory code of the CCIB-certified factory;

   b. Require that the factory lot or production lot number be on each shipping carton of the daily-use ceramicware that is to be exported to the United States;

4. Inspect and analyze factory lots or production lots of daily-use ceramicware to be

exported to the United States at a rate commensurate with the compliance history of the CCIB-certified factory and sufficient to provide a high degree of confidence that the daily-use ceramicware exported to the United States is in compliance with the Criteria;

5. Ensure that the CCIB laboratories that test daily-use ceramicware to determine its compliance with the Criteria follow the analytical procedures as described in the ANALYTICAL METHODOLOGY set forth in Attachment A;

6. Authorize the export of and issue export certificates for daily-use ceramicware intended for export to the United States, as indicated by either directly or transshipped through Hong Kong or other countries either by the manufacturer or by the importer/exporter, only for those delivery lots that are in compliance with the Criteria;

7. Require that all shipments of daily-use ceramicware intended to be exported to the United States via Hong Kong or other countries, as indicated by either the daily-use ceramicware manufacturer or the importer/exporter, be sealed by the CCIBs in such a way as to help prevent opening during transit;

8. a. Work with manufacturers and CCIBs to find solutions to any problems found when daily-use ceramicware from a CCIB-certified factory and covered by this MOU are determined by FDA not to meet the Criteria;

   b. Conduct an investigation if a daily-use ceramicware product from a CCIB-certified factory is detained by FDA because of an analytical finding of excessive levels of leachable lead or cadmium, to determine the cause of the technical defect that led to the violation and how it was remedied. SAIQ will provide FDA with a full report, in English, within three months of notification, on the findings of the investigation and the corrective measures taken to ensure future compliance;

9. Furnish FDA, upon request, with a copy, in both Chinese and English, of the current procedures and regulations relevant to daily-use ceramicware production/export and of the procedures/quality control plans used to ensure that each production lot of daily-use ceramicware is in compliance with United States FDA requirements;

10. Encourage the development and use of lead-free and cadmium-free decals, glazes and pigments in daily-use ceramicware and Chinese traditional ceramicware production; and,

11. Prevent, to the extent practicable, the export to the United States of ceramicware

which is not produced in a CCIB-certified factory, such as Chinese traditional ceramicware.

It is recognized by FDA and SAIQ that a period of four (4) months from date of signature will be necessary for SAIQ to complete certification procedures and logistical arrangements for all ceramicware factories which qualify for participation under the terms of this MOU. Therefore, SAIQ will provide FDA will the names, addresses and codes, as specified in Section III, A., as they are certified by SAIQ during the initial four-month implementation period.

B. THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

FDA intends to:

1. Sample and analyze certified delivery lots of daily-use ceramicware produced in CCIB-certified factories, and offered for entry into the United States to ensure that such lots exported from the People's Republic of China and offered for entry into the United States comply with the laws of the United States administered by the FDA;

2. Adjust its electronic entry processing system and conduct surveillance monitoring of daily-use ceramicware from CCIB-certified factories at a rate consistent with the Agency's confidence in the effectiveness of the SAIQ/CCIB factory certification system, so that the may proceed rate can be substantially higher for daily-use ceramicware firms identified/certified by SAIQ/CCIB as consistently producing and exporting daily-use ceramicware in accordance with this MOU than the may proceed rate for other Chinese daily-use ceramicware firms not so identified and certified;

3. Sample and analyze delivery lots of daily-use ceramicware from manufacturers not on the list of factories certified by the CCIB at a relatively high review and sampling rate consistent with the FDA's concern about possible lead and cadmium contamination of daily-use ceramicware from these uncertified factories, and place such firms on detention without physical examination when it appears that the firms do not meet FDA's requirements;

4. Detain, at FDA discretion, without physical examination, subsequent delivery lots of daily-use ceramicware from a CCIB-certified factory whose products appear to be, through previous analysis, in violation of the United States laws administered by the FDA. All daily-use ceramicware from a CCIB-certified factory that produces violative daily-use ceramicware may remain subject to detention without physical examination until such time as the SAIQ provides assurance to FDA's satisfaction that appropriate corrective actions have been implemented, and that

future daily-use ceramicware products from that factory will be in compliance with the Criteria. This assurance includes the report of Section III., A., 8., b., above. FDA may then resume review of ceramicware from the CCIB-certified factory, consistent with the provisions in III.B.2, above;

5. Promptly notify SAIQ and the First Secretary (Commercial) of the Embassy of the People's Republic of China in the United States of any delivery lot or portion thereof of ceramicware covered by this MOU that is detained for failure to comply with United States law. This notification, by the International Activities Staff of FDA's Center for Food Safety and Applied Nutrition, should include:

   a. The CCIB-certified factory number;

   b. A copy of the accompanying CCIB certificate or certificate number;

   c. Production Lot number;

   d. Quantity of daily-use ceramicware detained;

   e. Commodity or the name of the product and the style number or pattern name;

   f. FDA's sample number;

   g. Date sample collected;

   h. Reason for detention, including the technical defect, e.g., defective color in decal, if known;

   i. Date of detention;

   j. FDA's District Office that detained the product and Port of Entry;

   k. Manufacturer/shipper name (Factory code, name and address); and

6. Provide advice to SAIQ concerning approaches or actions that may be taken by the manufacturer/shipper of the detained product to help ensure that subsequent shipments will not be detained.

7. On an annual basis, provide SAIQ with results of any FDA analyses of daily-use and other ceramicware offered for import into the United States from the People's Republic of China.

IV. TECHNICAL INFORMATION EXCHANGE

The Parties agree to share expertise, provide assistance, and exchange information. Such mutual cooperation may include, but shall not be limited to:

A. Sharing current, new, and improved methods of sampling and testing of daily-use ceramicware for lead and cadmium;

B. Sharing current, proposed, or modified regulations or legislation related to daily-use ceramicware;

C. As resources permit, the exchange of administrative, regulatory, and scientific personnel knowledgeable about daily-use ceramicware;

D. The exchange of information about daily-use ceramicware quality control operations, plans, and procedures, including summaries of inspections, samples and analytical results; and

E. The exchange of data and research related to major food-caused health concerns that may be attributed to lead and cadmium.

V. SAMPLE COLLECTION

Whenever practicable, FDA intends to use the same representative sample to determine adherence with the Criteria. A representative sample will generally consist of:

Six (6) units of identical size, shape, color, decoration, and glaze collected from each sampled delivery lot.

VI. ADMINISTRATIVE PROCEDURES

The Parties shall mutually agree on the ways and means of giving instruction and guidance for the practical implementation and application of this MOU. All travel and per diem expenses incurred by one of the Parties in the course of providing technical assistance or other non-regulatory activities requested by the other Party in accordance with this MOU will be borne by the requesting Party, upon receipt from the providing party of an itemized statement of account.

The Parties shall designate points of contact under this MOU. The Parties shall notify each other of the points of contact by letter.

VII. PERIOD OF AGREEMENT AND TEXTUAL VERSIONS

This MOU will enter into force upon signature by both Parties and will continue for five (5) years. The Parties agree to evaluate the MOU during the five-year period. It may be extended or amended by written consent of the Parties. It may be terminated by either Party upon 30-days written notice to the other.

This MOU is done in duplicate, in the Chinese and English languages, both being equally authentic.

Signed at:

WASHINGTON, DISTRICT OF COLUMBIA

ON May 20, 1999

FOR THE STATE ADMINISTRATION OF ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA:

Shi Jianxin
Minister-Counselor (Commercial)
Embassy of the People's Republic of China

and

WASHINGTON, DISTRICT OF COLUMBIA

ON May 20, 1999

FOR THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA:

Sharon S. Holston
Deputy Commissioner for International and Constituent Relations

ATTACHMENT A

ANALYTICAL METHODOLOGY

Compliance with the Criteria in Attachment B will be determined by using the analytical method Standard Method for Lead and Cadmium Extracted from Glazed Ceramic Surfaces described in the latest edition of *Annual Book of ASTM Standards*, of the American Society for Testing and Materials (ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959), currently volume 15.02 (1996), designation C738-94.

The method also appears in the March 1996 Supplement to the 16th Edition of *Official Methods of Analysis* (AOAC International, 481 N. Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2417). Method 973.32 is used for high levels, Method 973.82 is used for low levels.

The levels of lead and cadmium are to be determined by analyzing each unit at the same time, individually, according to the above cited method.

ATTACHMENT B

CRITERIA FOR CERTIFICATION FOR EXPORT OF DAILY-USE CERAMICWARE

SAIQ agrees not to certify ceramicware factories that produce daily-use ceramicware for export to the United States that contain levels of lead or cadmium that exceed the following United States Food and Drug Administration guidance that is non-discriminatory, and applies without distinction to domestic and imported products:

A. LEAD

Category	Action Basis	Maximum Level* micrograms/mL
Flatware	Average of 6 units	3.0
Small Hollowware other than cups, mugs and pitchers	Any one of 6 units	2.0
Cups and mugs	Any one of 6 units	0.5
Large Hollowware other than pitchers	Any one of 6 units	1.0
Pitchers	Any one of 6 units	0.5

B. CADMIUM

Category	Action Basis	Maximum Level* micrograms/mL
Flatware	Average of 6 units	0.5
Small Hollowware	Any one of 6 units	0.5
Large Hollowware	Any one of 6 units	0.25

* Micrograms of element per milliliter of four percent (4%) acetic acid leaching solution as per cited analytical method.

[FR Doc. 99–19106 Filed 7–17–99; 8:45 am]
BILLING CODE 4160–01–C