MEMORANDUM OF UNDERSTANDING

Between The

FEDERAL GRAIN INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE

And The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

1. PURPOSE

This agreement sets forth the working arrangements between the Federal Grain Inspection Service (FGIS) and the Food and Drug Administration (FDA) regarding their respective responsibilities in the inspection and standardization of grain, rice, pulses, and food products. *

II. BACKGROUND

This Memorandum of Understanding revises and replaces the Memorandum of Agreement on this subject which went into effect on April 15, 1980.

III. STATUTES RELATING TO THE AGREEMENT

A. The Food and Drug Administration of the Department of Health and Human Services enforces the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (the act). In fulfilling its responsibilities under the act, FDA insures that foods, including animal feed, are safe and wholesome and are labeled in a truthful, nonmisleading manner. FDA accomplishes this in part, by inspecting facilities that process, hold, and distribute grain, rice, pulses, and similar food. FDA also examines samples of inspected food to determine whether the food is adulterated or misbranded within the meaning of the act. FDA also promulgates, under the act, standards of identity, quality, and fill of container for food products.

* This agreement applies only to those commodities assigned to FGIS by the Secretary of Agriculture.

B. The Federal Grain Inspection Service of the U.S. Department of Agriculture under the authority of (1) the U.S. Grain Standards Act (7 U.S.C. 71 et seq.) and the regulations thereunder (7 CFR Part 800 through 810), and (2) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) and the regulations thereunder (7 CFR Part 68), performs voluntary and mandatory inspection and weighing services designed to aid in the efficient marketing of agricultural products. These services include developing specifications and standards; furnishing inspection, grading, and weighing services; and issuing certificates of quantity, quality, and condition of producers, processors, shippers, buyers, and other interested parties. An FGIS certificate provides reliable commercial information concerning the quantity, quality, and condition of agricultural products.

IV. SUBSTANCE OF AGREEMENT

A. When performing functions under the act that relate to agricultural products, persons, and facilities that are also subject to the laws and regulations administered by FGIS, FDA will:

1. During FDA inspection of a facility that processes, packs, or holds agricultural products, request the FGIS inspector or FGIS licensee stationed at a facility, to accompany the FDA inspector during the inspection. The FDA inspector will discuss with the FGIS inspector or FGIS licensee any conditions that the FDA inspector believes may result in violations of the act.

2. Request FGIS to furnish information concerning quality determinations of specific lots of products against which FDA has taken or may take action. When involved in such an action FDA will consider the results of official FGIS inspection certificates and other available data provided the information is relevant to the current condition of the product and the nature of the violation charged.

When an FDA action is to be based on an analysis by FGIS or an FGIS licensee and FDA has not received the results of an appeal analysis, FDA through its appropriate field office will contact the designated FGIS field liaison person (see IV.B.4.), confirm that an appeal analysis is being conducted and request an oral report of the results of the analysis as soon as possible.

3. Notify FGIS concerning details of objectionable conditions found by FDA to exist in processing plants, packing plants, grain elevators, or any other facilities where FGIS provides official services.

4. Notify FGIS of the criteria FDA uses to determine whether FDA should consider an action under the act against an agricultural product. Notification will ensure that FGIS does not classify an objectionable commodity as acceptable.

5. Upon request of FGIS, review for possible conflict with the misbranding provisions of the act the following: labels, legends, stamps, and other marks on products that are packed under the various official services.

B. When performing functions under the laws and regulations administered by FGIS that relate to agricultural products, persons, and facilities that are also subject to the act, FGIS will:

1. Promptly notify FDA of the facilities that are subject to withdrawal or suspension of service, termination of contract, or denial of official FGIS services because of insanitary conditions or other processing deficiencies.

2. Investigate any report from FDA that a processor, packer, merchandiser, or facility operator using official FGIS services has not corrected objectionable conditions found by FDA. Upon completion of this investigation, FGIS will initiate appropriate action and notify FDA of the action taken.

3. Refuse to inspect products which have been seized by FDA or which are known to be involved in formal FDA actions. This does not preclude official reinspection of authorized samples if the FDA action involves products which have been officially inspected.

4. Promptly report to FDA the results of any inspection or analysis (including results of any appeal analysis, when available) for any product that may be actionable under the act. Such report shall include information to assist in locating and identifying the product and the name of an appropriate field liaison person in FGIS.

5. Furnish FDA, upon request, any pertinent information concerning the grade or quality of FGIS inspected specific lots of products, against which FDA has taken or may take action.

C. It is mutually agreed that:

1. Field liaison will be maintained between FDA District offices and FGIS designated field liaison persons as indicated in IV.B.4. General matters involving this agreement may be referred to the agencies' liaison officers as indicated in VI.A. and VI.B.

2. Proposed regulations initiated by either agency which affect, establish, or amend food standards or other products covered by this agreement will be referred to the other agency for review and comment before the proposed regulations are published for broader comment.

3. Both agencies will cooperate with industries in improving sanitation and food handling practices in processing plants, packing plants, or other facilities.

4. Both agencies will exchange data and cooperate in developing sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products officially inspected.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

A. Federal Grain Inspection Service
U.S. Department of Agriculture
14th St. and Independence Ave.,
Washington, DC 20250.

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857.

VI. LIAISON OFFICERS

A. For the Food and Drug Administration:

Director, Office of Compliance,
(currently, John M. Taylor),
Center for Food Safety and Applied Nutrition (HFF-300),
200 C St. SW.,
Washington, DC 20204,
202-485-0160.

B. For the Federal Grain Inspection Service:

Director, Field Management Division,
(currently, John W. Marshall),
Federal Grain Inspection Service,
14th St. and Independence Ave.,
Washington, DC 20250,
202-382-0228

VII. PERIOD OF AGREEMENT

This agreement, when accepted by both parties, will be effective indefinitely. It may be modified by mutual consent or terminated by either party upon a 30-day written notice.

APPROVED AND ACCEPTED FOR THE FEDERAL GRAIN INSPECTION SERVICE

BY: /S/
K.A. Gilles

TITLE: Administrator
Federal Grain Inspection Service

DATE: October 9, 1985

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

BY: /S/
Joseph P. Hile

TITLE: Associate Commissioner
for Regulatory Affairs

DATE: Nov. 8, 1985