Dated: February 3, 1995,

Ronald G. Chesemore.

Associate Commissioner for Regulatory Affairs.

Memorandum of Understanding Between U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration and Environmental Protection Agency, Gulf of Mexico Program

Purpose:

This Memorandum of Understanding (MOU) is to establish the working arrangements and responsibilities of the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) for the purpose of FDA providing a liaison to the EPA Gulf of Mexico Program Office.

Background:

The Gulf of Mexico Program (GMP) was established under the leadership of EPA to develop a comprehensive, intergovernmental strategy to protect and enhance the environmental quality of the Gulf of Mexico. The GMP identified priority issues of environmental degradation and concern, established a Gulf-wide committee framework and infrastructure to ensure communication and information exchange and began implementing a 5-year strategy. The strategy includes:

- 1. Preparation of environmental characterization reports,
- 2. Preparation of environmental assessments,
- 3. Development of an interactive data management system,
- 4. Preparation of predictive assessments,
- 5. Development of environmental measurement plans and
- 6. Development of an environmental monitoring system.

FDA's Office of Seafood was established to strengthen the agency's domestic and imported seafood programs. The Office of Seafood coordinates all of FDA's seafood activities, including those which assure that seafood does not contain harmful amounts of natural or man-made substances, such as toxins, pathogenic microorganisms, industrial chemicals or toxic metals. FDA uses several strategies to accomplish its public health mission. One strategy is to assist EPA in its Gulf of Mexico Program.

- A. The Food and Drug Administration agrees to:
- 1. Assign one individual to serve as the principal liaison between FDA and the Gulf of Mexico Program (GMP) with responsibility for managing, coordinating, implementing and evaluating FDA activities in support of the GMP. The FDA liaison:

- a. Provides program and technical assistance and coordination of FDA activities with the GMP Technical Steering Committee, Policy Review Committee, technical steering subcommittees and the State, local and Federal agencies participating in the GMP.
- b. Serves as Federal Co-Chair of the Public Health Subcommittee with primary responsibility for developing a Public Health Action Plan for the Gulf of Mexico Program and incorporating the recommendations of the National Academy of Sciences Report on Seafood Safety. The plan should address four major elements, three of which are problems for which FDA has the lead:
- (1) Illnesses associated with consumption of raw shellfish as a result of naturally occurring pathogens and/or pathogens of fecal origin.
- (2) Risks associated with consumption of Gulf of Mexico seafood contaminated with toxic substances or pesticides.
- (3) Effects of naturally occurring marine biotoxins on the public health through direct exposure via aerosols and/or exposure via contaminated Gulf seafood.
- (4) Illness associated with recreational or occupational use of ambient waters contaminated with sewage.
- c. Coordinates, with other GMP participants, the five major aspects of the GMP study: Resource characterization and assessment; problem identification and study design; communication and education; integration with ongoing programs of the Gulf; and development of management, implementation and monitoring strategies.
- d. Evaluates technical documents developed by the Technical Steering Subcommittees and other agencies as they relate to public health and GMP issues and for consistency with FDA policies, programs and regulations.
- e. Works closely with States to promote cooperation and harmonization of their public health programs as they relate to Gulf of Mexico issues.
- f. Serves as the FDA point of contact with the National Shellfish Pollution Indicator Study. Is responsible for keeping the GMP informed of developments and providing program needs to the Indicator Study directors.
- g. Develops appropriate projects to evaluate programs and methods of reducing public health risks associated with the use of the waters and resources of the Gulf of Mexico.
- h. Serves as project officer on extramural projects to conduct scientific studies of interest to FDA which relate to the Gulf of Mexico Program.
- 2. Provide the following administrative support to the assigned individual:

- a. *Salary*—The FDA employee will remain on the FDA payroll for the entire period of the assignment.
- b. *Relocation Expenses*—The cost of relocating the FDA employee to the John C. Stennis Space Center, Mississippi, as provided by policies and procedures relating to reporting to a duty station.
- c. *Travel Expenses*—The FDA employee will be provided transportation and per diem expenses while in temporary duty status for the entire period of the assignment.
- d. *Equipment*—FDA will provide a personal computer for use by the employee during the entire period of the agreement.
- 3. Provide annual review of the individual's performance for the entire period of the assignment.
- 4. Administrative Support—Annually provide partial financial support to EPA/GMP to defray part of the overall costs to them for providing services as stated under this IAG. Amount to be worked out between the two agencies.
- B. The Environmental Protection Agency-Gulf of Mexico Program agrees to:
- 1. Provide technical supervision and assign day-to-day tasks to the FDA representative to the GMP. The technical and day-to-day assignments will be provided by the Director of the Gulf of Mexico Program; and he shall serve as the EPA's point of contact and the liaison officer for this interagency agreement.
- 2. Provide the following administrative support to the assigned individual:
 a. Space—Space will be provided at the GMP Headquarters at the John C. Stennis Space Center; and the space will contain appropriate furniture and conveniences.
 b. Telecommunication—Telephone service including FTS, Long Distance, and Fax will be provided.
- c. Secretarial Support—Secretarial support will be provided to include: Typing, xeroxing, dictating, filing, printing, duplicating, and office supplies.
- 3. The Director, GMP, will provide FDA with written comments on the individual's performance for the specified rating period. The information will be used on the General Workforce Performance Appraisal of the FDA liaison.

Period of Agreement:

It is anticipated that this MOU will be for approximately 5 years from the date of signature. Modification of the MOU shall be by mutual consent of the parties. However, if either party desires to terminate this MOU, a written notice to the other party shall be forwarded and received 30 days in advance of the desired termination date.

Approved and Accepted for the Environmental Protection Agency Gulf of Mexico Program

By: Douglas A. Lipka Title: Acting Director Date: September 29, 1994

Approved and Accepted for the Food and Drug Administration

By: Fred R. Shank Title: Director, Center for Food Safety and Applied Nutrition