

225-03-8001 (formerly 225-00-8000)

MEMORANDUM OF UNDERSTANDING

Between the

FOOD AND DRUG ADMINISTRATION

And the

CENTERS FOR DISEASE CONTROL AND PREVENTION**I. PURPOSE**

This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) provides a framework for coordination and collaborative efforts between these two agencies which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information exchanges between FDA and CDC shall take place.

This memorandum supersedes the Memorandum of Understanding Between the Centers for Disease Control and the Food and Drug Administration, dated 6/26/00, regarding the exchange of information and coordination of actions.

II. BACKGROUND

FDA and CDC are sister agencies within the Department of Health and Human Services. Both FDA and CDC exist and work to protect the public health but have different statutory mandates and responsibilities.

FDA is a regulatory agency responsible for protecting the public health through the regulation of food, cosmetics, and medical products, including human drugs, biological products, animal drugs, and medical devices. FDA administers the Federal Food, Drug, and Cosmetic Act and relevant sections of the Public Health Service Act, among other statutes. Among its duties, FDA approves pre-market applications, conducts inspections of manufacturing facilities, and monitors post-marketing adverse events. FDA also initiates civil and criminal litigation to enforce applicable laws and regulations.

CDC is charged with protecting the public health by providing leadership and direction in the prevention and control of diseases and other preventable conditions and by responding to public health emergencies. CDC administers relevant sections of the Public Health Service Act, the Occupational Safety and Health Act, the Clinical Laboratory Improvement Act, and the Federal Mine Safety and Health Act. CDC, among other activities, administers national programs for the prevention and control of communicable and vector-borne diseases, enforces quarantine regulations, and works