

## MEMORANDUM OF UNDERSTANDING

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

AND THE  
HEALTH PRODUCTS AND FOOD BRANCH  
HEALTH CANADA  
OF CANADA

REGARDING SHARING AND  
EXCHANGE OF INFORMATION ABOUT THERAPEUTIC PRODUCTS

## PREAMBLE

The Food and Drug Administration (USFDA), Department of Health and Human Services of the United States of America and the Health Products and Food Branch (HPFB), Health Canada of Canada (collectively "the Participants") recognize the importance of timely and effective communication and collaboration between U.S. and Canadian governmental authorities. These communications are especially important on matters relating to the safety, quality, and efficacy of therapeutic products. Therapeutic products are defined as: pharmaceutical products for human and animal use (including active pharmaceutical ingredients, finished dosages and radiopharmaceutical products); biological products for human use (including gene, cell, blood, tissue, and organ therapies and products intended for transplantation or transfusion; vaccines; xenografts); and medical devices for human and animal use. The Participants share a mutual high regard for the critical role of one another's regulatory systems in the review and approval of these products. To that end, the Participants to this Memorandum of Understanding (MOU) intend to establish mechanisms by which the sharing and exchange of documents and/or information between staffs relating to the review and evaluation of investigational and marketing applications, establishment compliance, and post-marketing surveillance of these products would be facilitated as decided to by the Participants.

## I. PURPOSE

This MOU is intended to enhance and strengthen the exchange of information and existing public health protection cooperative activities related to the regulation of the specified therapeutic products.