

Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0590.
SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c),

which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 18, 2003.
Jeffrey Shuren,
Assistant Commissioner for Policy.
BILLING CODE 4160-01-S

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA
AND
SWISSMEDIC
OF THE SWISS CONFEDERATION
REGARDING
EXCHANGE OF INFORMATION ABOUT PHARMACEUTICAL PRODUCTS FOR
HUMAN AND ANIMAL USE, AND MEDICAL DEVICES

PREAMBLE

The Food and Drug Administration (FDA), of the United States Department of Health and Human Services (HHS) and Swissmedic (collectively "the Participants") recognize the importance of timely communication between U.S. and Swiss governmental authorities. These communications are especially important on matters relating to the safety, quality, and efficacy of: (a) pharmaceutical products for human use (including active pharmaceutical ingredients and finished dosage products and biological products, such as vaccines and blood products); (b) pharmaceutical products for animal use (not including biological products for animals because FDA/HHS and Swissmedic do not have oversight authority for such products in the United States of America or Switzerland respectively); and (c) medical devices for human 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 for marketing. To that end, the Participants to this Memorandum of Understanding (MOU) intend to establish mechanisms by which the exchange of documents and/or information between staffs during the review and evaluation of investigational and marketing applications and the post-marketing surveillance of these products would be facilitated as agreed to by the Participants.

I. PURPOSE

This MOU is intended to further enhance and strengthen communication and existing public health promotion and protection cooperative activities related to the regulation of human or animal pharmaceutical products and human medical devices in Switzerland and the United States of America.