

III. CONFIDENTIALITY

Information exchanged under this MOU may include non-public information exempt from public disclosure under the laws and regulations of Switzerland or the United States of America. Information that is not appropriate for public dissemination will be shared according to the procedures and policies of the Participants as permitted by their respective laws. FDA/HHS and Swissmedic are not able to share trade secret information without the consent of the owner of the information. With regard to any other types of non-public information that may be provided to Swissmedic by FDA/HHS or to FDA/HHS by Swissmedic, such transmissions will be made in accordance with the specific signed confidentiality commitments and other requirements of the Participants.

The personnel of the agencies shall be required, even after their duties have ceased, not to disclose non-public information acquired under this MOU, including information which is of the kind covered by the obligation of professional secrecy in Switzerland and information and activities covered by 18 U.S.C. § 207 in the United States of America.

IV. SOURCE OF FUNDING

Each Participant to this MOU intends to fund its own activities subject to the availability of appropriated funds, personnel, and other resources. Any exchange of information or other activity under this MOU is to be performed in accordance with applicable laws and regulations.

V. DURATION

Cooperation under this MOU commences upon signature of the Participants and continues in effect for a period of ten (10) years unless modified by mutual consent of the Participants or terminated earlier by either Participant upon a 30 calendar-day written notification to the other Participant.

After the first year of operation, the Participants may jointly evaluate the MOU. Periodic reviews may be conducted as deemed necessary by the Participants. The MOU may be extended for additional 10-year periods, with periodic reviews as needed and agreed to by the Participants.

This MOU does not modify existing cooperative activities nor does it preclude entering into separate arrangements for special programs that can be handled more efficiently and expeditiously by special arrangements.

Nothing in this MOU is intended to diminish or otherwise affect the authority of either Participant to conduct its regulatory responsibilities and programs. In addition, no provision of this MOU restricts either Participant from conducting its own inspection of a pharmaceutical or medical device manufacturing facility within the jurisdictional boundaries of the other country when needed to meet the needs of its own pharmaceutical or medical device regulatory program.