MEMORANDUM OF UNDERSTANDING

BETWEEN

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

AND

THE HEALTH SCIENCES AUTHORITY
OF THE REPUBLIC OF SINGAPORE

ESTABLISHING THE MEDICAL PRODUCTS WORKING GROUP

1. PREAMBLE AND PURPOSE

The Medical Products Working Group (MPWG) is established under Annex 6A of the United States - Singapore Free Trade Agreement (US-S FTA) to promote the protection of public health through expeditious, science-based regulatory procedures for new medical products. The US-S FTA requires the Food and Drug Administration of the United States of America (FDA) and the Health Sciences Authority of Singapore (HSA) (hereinafter referred to as the "Participants") to report on the activities of the MPWG to the Secretary of Health and Human Services of the United States of America and to the Minister for Health of the Republic of Singapore respectively.

The purpose of the MPWG is to provide a forum for cooperation on product regulation issues of mutual interest, to the extent permitted by resources, through means other than mutual recognition agreements or other binding commitments. The Participants intend that their cooperation under this Memorandum of Understanding (MOU) include collaboration on the regulation of medical products, namely human drug products (medicines, biologics, and botanical drugs) and medical devices.

2. COMPOSITION OF THE MEDICAL PRODUCTS WORKING GROUP

The Participants intend that the MPWG be jointly chaired by the Commissioner of Food and Drugs (FDA), and the Chief Executive Officer (HSA), or any senior officer appointed by the respective Chairpersons.

The Participants intend that the MPWG function primarily as a steering committee for activities undertaken under this MOU. The Participants intend that the MPWG comprise senior management and senior scientific staff of HSA and FDA, and that the specific number of people on the MPWG be agreed by the Participants.

Each Participant intends to designate a single point of contact for the activities undertaken under this MOU.

The MPWG may form one or more sub-committee(s) to ensure smooth and effective coordination or implementation of any plans, programs, or activities.

3. MEETINGS AND CORRESPONDENCE

In addition to on-going communication via telephone, teleconferences, videoconferences or written correspondence, designated representatives of the MPWG expect to meet face-to-face at least once every year.

4. AREAS OF COOPERATION

The MPWG should seek to establish areas of cooperation to include, for example, exchange of information, enhancement of professional competencies, and scientific collaborations. The areas of cooperation may be changed at any time by mutual consent of the Participants.

5. IMPLEMENTATION WORK PLAN

The MPWG intends to establish an Implementation Work Plan, setting out the arrangements to be applied for the activities undertaken under this MOU, including the commencement date(s) and duration, as well as any other matters deemed necessary for the efficient execution and management of these activities.

6. SECRETARIAT SUPPORT

The Participant hosting any specific activity intends to provide secretariat support and services as needed.

7. CONDITIONS OF EXCHANGE OF INFORMATION

The Participants may execute Confidentiality Commitments relating to the non-disclosure of non-public information.

8. COMMENCEMENT AND AMENDMENT

It is intended that activities under this MOU commence upon signature by both Participants. It is intended that the MOU be in effect for five (5) years, and may be extended with the written consent of both Participants. The Participants may evaluate the MOU during the five-year period, and may amend it by written consent of both Participants, specifying the date on which the amendments are to take effect. All activities of FDA and HSA undertaken pursuant to this MOU are to be conducted respectively in accordance with the laws and regulations of the United States of America and Singapore and are subject to the availability of personnel, resources, and appropriated funds. This MOU is not intended to create any obligation under international or other law.

Signed in Rockville, Maryland on this the 24th day of June, 2005 in duplicate in the English language.

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

LESTER M. CRAWFORD, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

FOR THE HEALTH SCIENCES AUTHORITY OF THE REPUBLIC OF SINGAPORE

TAN CHOR HIANG, M.B.B.S.

Chief Executive Officer