STATEMENT OF COOPERATION BETWEEN THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THE PHARMACY AND POISONS BOARD REGARDING COOPERATION TO ENHANCE ACTIVITIES OF MUTUAL INTEREST

The United States Food and Drug Administration (FDA) and the Pharmacy and Poisons Board (PPB), Kenya (collectively "the Participants") recognize the importance of timely and effective communication and collaboration, and information exchange in the promotion and protection of public health. The Participants share a mutual high regard for the critical role of their respective regulatory systems in the products each regulates and are committed to strengthening their longstanding bilateral cooperation.

I. PURPOSE

This Statement of Cooperation (SOC) is intended to strengthen existing structures and develop new opportunities for cooperative engagement and enhanced capacity in regulatory matters and public health protection that are related to the products the Participants regulate.

II. SCOPE

This SOC covers products regulated by, and efforts and activities within the mandate of, both Participants. The Participants intend to explore a mechanism(s) for regular meetings and other types of engagements for the development of plans for exchanging information and strengthening regulatory cooperation.

The Participants, in accordance with their respective laws and regulations, expect to work together as appropriate to implement the intent of this SOC. This work is intended to facilitate the effective exchange of information, develop new or strengthen existing cooperative efforts/initiatives, and coordinate, when appropriate, with stakeholder groups relevant to product regulation within their respective countries.

III. CONFIDENTIALITY

The Participants expect that most of the information exchanged under this SOC may be provided in a form appropriate for public dissemination under the laws governing the transmitting Participant. Any non-public information exempt from public disclosure should only be shared as permitted by the laws and regulations governing the Participants and under the appropriate confidentiality commitments and disclosure procedures and policies of the Participants.

IV. SOURCE OF FUNDING

Each Participant recognizes the other's responsibility to fund and implement its respective activities subject to the availability of appropriated funds, personnel, and other resources. Special arrangements for funding of selected activities may be made by appropriate mutual decision.

V. NON-BINDING INTENT

This SOC is not an international agreement and is not intended to create binding obligations under international or domestic law. Nothing in this SOC is intended to negatively affect the Participant's responsibility or ability to carry out its regulatory activities and programs in accordance with their respective laws and regulations.

No provision of this SOC restricts either Participant from conducting its own regulatory activities within the jurisdictional boundaries of the other country when necessary to meet the needs of its own regulatory programs and/or individual missions.

VI. DURATION AND PROCESS

This SOC may commence upon the Participants' last signature and is intended to remain effective for a period of five (5) years. Thereafter, the Participants may extend this SOC for successive five-year periods. The SOC may be modified by mutual written decision of the Participants and may be discontinued by either Participant. A Participant should give sixty (60) calendar days' written notice to the other Participant of its intent to discontinue implementation.

UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA):

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