STATEMENT OF COOPERATION

BETWEEN

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

AND

THE NATIONAL HEALTH SURVEILLANCE AGENCY OF BRAZIL

REGARDING COOPERATION TO ENHANCE ACTIVITIES OF MUTUAL INTEREST

The United States Food and Drug Administration (FDA) and the National Health Surveillance Agency of Brazil (ANVISA) (collectively "the Participants") recognize the importance of timely and effective communication and collaboration. The Participants share a mutual high regard for the critical role of their respective regulatory systems in the products each regulates. The Participants intend to strengthen existing cooperation in scientific and regulatory areas.

I. PURPOSE

This Statement of Cooperation (SOC) is intended to strengthen existing structures and develop new opportunities for cooperative engagement in regulatory and scientific 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 under 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 other countries and with stakeholder groups relevant to product regulation within their respective countries or a broader global context.

The activities planned and performed under this SOC may include, but are not limited, to the following:

A. Explore the development of specific procedures for the exchange of regulatory and public health information for routine and/or emergency purposes;

B. Identification of research endeavors and studies to support the scientific basis for regulatory requirements and actions that are of mutual interest;

C. Consider the exchange of information resulting from investigations, in progress or completed, that are conducted by the Participants when their investigations are related to product-associated risks; and

D. Exploration of synergies, to the extent possible, where the Participants' involvement could help to guide and facilitate opportunities for capacity building/systems strengthening and implementation of harmonized science-based standards of mutual interest and benefit to the Participants.

E. Collaboration to increase understanding and knowledge base(s) about each Participant's respective regulatory systems, and whenever possible, explore opportunities for leveraging the Participants' respective resources in ways that help to expand the safety net for the products the Participants regulate.

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. Each Participant should share non-public information exempt from public disclosure according to the procedures and policies of the Participant as permitted by the laws governing the Participant.

IV. SOURCE OF FUNDING

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

V. NON-BINDING INTENT

This SOC 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' signatures and is intended to continue for a period of five (5) years. The Participants may modify this SOC, by mutual decision in writing, specifying the date the modifications are intended to commence. Implementation of this SOC may be extended as decided by the Participants.

Implementation of this SOC may be discontinued by either Participant. A Participant should endeavor to give sixty (60) calendar days' written notice to the other Participant of its intent to discontinue implementation.

Signed in Brasília, Brazil, on this 26th day of November 2012, in the English and Portuguese languages.

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