STATEMENT OF INTENT
BETWEEN
THE FOOD AND DRUG ADMINISTRATION OF
THE UNITED STATES OF AMERICA
AND
THE MINISTRY OF HEALTH AND FAMILY WELFARE OF
THE REPUBLIC OF INDIA
ON CO-OPERATION IN THE FIELD OF MEDICAL PRODUCTS

The United States Food and Drug Administration (FDA) and the Ministry of Health and Family Welfare (MoH&FW) of the Republic of India, hereinafter collectively referred to as the "Participants," and individually referred to as "Participant".

- Acknowledging that the Participants seek to strengthen bilateral cooperation in the area of regulatory systems for medical products, to promote and protect public health;

- Acknowledging that the safety, effectiveness, manufacturing quality, and/or security of human and veterinary medicines, human vaccines and other biological products, cosmetics, and medical devices including diagnostic devices are responsibilities common to national regulatory authorities;

- Understanding that there is a need in the interest of public health to establish dynamic and effective collaboration to strengthen and achieve convergence in regulations in keeping with international standards;

- Acknowledging the importance of safe medical products, to saving lives, restoring health, treating and preventing diseases;

- Recognizing the growing public health interest in raising public awareness of, and in the dissemination of accurate, science-based information about, medical products manufacturing quality, effectiveness, safety and security;

- Acknowledging the importance of long-term global collaborations to help ensure timely and secure availability of quality, safe, and effective medical products to consumers, and to prevent the distribution of substandard or unsafe medical products and unsafe cosmetics;

- Sharing the common objectives of improving the safety, effectiveness and manufacturing quality of medical products, in the United States of America and the Republic of India;

- Sharing the common belief that a knowledge of clinical safety and effectiveness of medical products is best determined through well-designed, scientifically robust, ethically-conducted clinical trials, and acknowledging the need to have in place systems to assure the appropriate oversight of human clinical trials:

- Recognizing the need to effectively address the challenges of the quality, safety, effectiveness and security, as appropriate, of medical products and cosmetics in a sustainable manner, and to work together towards achieving these goals;

- Acknowledging that both countries, within their respective national circumstances, capacities and laws, can work together to promote effective and sustained outcomes to strengthen public health through appropriate regulatory efforts as well as effectiveness and transparency;

Hereby express the following intentions.

1. Within the framework of this Statement of Intent and taking into account the limitations of existing human and financial resources and within the parameters of domestic legal and administrative requirements the Participants expect to cooperate in the following areas:

   - Sharing of information relevant to lack of compliance with accepted current Good Manufacturing Practice, Good Clinical Practice, or Good Laboratory Practice, as appropriate, by manufactures and sponsors of medical products and manufacturers of cosmetics, in one another's country, or any other information as mutually decided upon.

- Engaging collaboratively as observers in medical and cosmetic product and inspections conducted by the other Participant as per specific terms to be agreed and as time and resources allow.

- Informing the respective regulatory authorities before undertaking inspections, so that host-country inspectors may join inspections as observers.

- Collaborating in relevant scientific meetings, symposia, seminars, and other appropriate venues that may be organized either in the United States of America or the Republic of India.

- Facilitating Participants' holding (in persons or by teleconference) periodic discussions, possibly once every three (3) months, to report and assess progress on current collaborations and implementation of this Statement of Intent, to address concerns and resolve issues leading to strengthening and improving the bilateral relationship, and to identify new areas for collaboration.

- Facilitating information-sharing between Participants as appropriate and allowable by law, in support of public health and product safety, quality, and effectiveness, as appropriate.

2. Each Participant intends to designate, within 60 (sixty) calendar days after the signing of this Statement of Intent, a primary Point of Contact (POC) for the Participant who will be responsible for facilitating routine and emergency communication.

3. Each Participant is expected to bear all of its respective costs for activities under this Statement of Intent, unless the Participants decide otherwise; in such instances, the Participants intend to prepare a document that sets forth financial and technical responsibilities of each Participant. When alternative funding mechanisms have been decided upon, the Participants intend that the specific activities are to commence only after said document is approved by the Participants.

4. This Statement of Intent does not create rights or obligations.

5. Cooperation under this Statement of Intent will commence on the date of its signature by both Participants and will continue for a period of five (5) years. This Statement of Intent may be modified at any time by mutual written consent of the Participants. Either Participant may terminate this Statement of Intent through written notice of not less than ninety (90) days to the other Participant. The Participants may also extend this Statement of Intent by exchange of letters for a further period of five (5) years.

Signed at New Delhi, on this 10th day of February 2014, in two originals in the English language.

ON BEHALF OF
THE UNITED STATES
FOOD AND DRUG ADMINISTRATION

Name: Margaret Hamburg, MD

Designation:

COMMISSIONER
FOOD AND DRUG ADMINISTRATION

ON BEHALF OF
MINISTRY OF HEALTH & FAMILY WELFARE OF THE REPUBLIC OF INDIA

Name: Keshav Desiraju

Designation: 10 Jan 14

SECRETARY
DEPARTMENT OF HEALTH & FAMILY WELFARE