

**MUTUAL CONFIDENTIALITY ARRANGEMENT
AND
COMMITMENT NOT TO PUBLICLY DISCLOSE
NON-PUBLIC INFORMATION SHARED
BY AND BETWEEN
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
AND
THE WORLD HEALTH ORGANIZATION
("the Arrangement")**

Whereas the United States Food and Drug Administration (FDA) and the World Health Organization, through its Department of Essential Medicines and Health Products (WHO/EMP) (jointly, "the Participants") are willing to disclose information to each other for the sole purpose of undertaking discussions aimed at coordinating and facilitating FDA's regulatory activities on the one hand, and the activities of WHO/EMP's International Nonproprietary Name (INN) Programme relating to the identification of pharmaceutical substances and active pharmaceutical ingredients on the other hand (hereinafter referred to as "the Purpose").

Whereas to this end, each Participant may (as "the Disclosing Participant") disclose to the other Participant (as "the Receiving Participant") certain information relating to its aforesaid activities that it considers non-public, confidential or proprietary to it or parties collaborating with it.

Whereas the aforesaid information may include information protected from public disclosure, such as confidential product and/or commercial information; trade secret information; personal privacy information; law enforcement information, and/or internal, pre-decisional information.

Any information of the type described in the previous paragraph and designated by FDA or WHO/EMP, as the case may be, as non-public, proprietary or confidential as aforesaid is hereinafter referred to as "Information."

Whereas FDA and WHO/EMP are willing to disclose Information to each other exclusively for the Purpose, subject always to the terms of this Arrangement.

Whereas FDA and WHO/EMP each affirm that they have the authority to protect Information from public disclosure.

Therefore, FDA and WHO/EMP each agree that any disclosure of Information by one Participant to the other will be subject to the following terms and conditions:

- a. Any Information which is supplied in written or other tangible form shall be clearly identified as subject to this Arrangement. Any Information which is disclosed in oral form shall be confirmed in written summary form within fifteen (15) days from the date of oral disclosure by the Disclosing Participant.
- b. The Information disclosed by the Disclosing Participant shall be treated by the Receiving Participant as strictly confidential. The Receiving Participant shall use such Information only for the Purpose and shall make no other use thereof unless and until written permission is granted by the Disclosing Participant and, where appropriate, the owner of the Information in question permits such other use(s) thereof. In connection with the foregoing, the Receiving Participant shall restrict access to Information received from the Disclosing Participant hereunder strictly to those persons within its organization (i.e., FDA or WHO/EMP, as the case may be) who have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement. For the avoidance of doubt and for purposes of this Arrangement, "persons within its organization" shall include: -
- For FDA: FDA officials and employees, including FDA Commissioned State Officials and Special Government Employees, and FDA contractors; and
- For WHO: WHO employees, experts, temporary advisors, consultants and contractors.
- c. The Receiving Participant will not publicly disclose Information from the Disclosing Participant without the prior written consent of the Disclosing Participant, and (where the Disclosing Participant is not the owner of the Information) the written authorization of the owner of such Information, or the written authorization from the individual who is the subject of the personal privacy Information, or a written statement from the Disclosing Participant that the Information is no longer subject to the obligations contained herein.
- d. Nothing in this Arrangement shall prevent the Disclosing Participant from disclosing its own Information to any third party.
- e. Nothing in this Arrangement shall be construed as a grant to the Receiving Participant of any rights to the Information.
- f. The Receiving Participant undertakes to maintain the Information received from the Disclosing Participant in confidence. In this regard, the Receiving Participant shall take all reasonable measures to ensure that the Information shall not be used for any purpose other than the Purpose, and shall only be disclosed to persons within its organization who have a need to know for the

Purpose (as defined above) and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement.

- g. The obligations of confidentiality and restrictions on use referred to above shall not apply to any part of the Information which the Receiving Participant is clearly able to, and does, demonstrate to the Disclosing Participant:
 - i. was lawfully in its possession and known to it (without any obligation of confidentiality) prior to disclosure by the Disclosing Participant (as evidenced by written records or other competent proof); or
 - ii. was in the public domain or the subject of public knowledge at the time of disclosure by the Disclosing Participant; or
 - iii. becomes part of the public domain or the subject of public knowledge through no fault of the Receiving Participant; or
 - iv. becomes available to the Receiving Participant from a third party not in breach of a legal obligation of confidentiality; or
 - v. was subsequently and independently developed by or on behalf of the Receiving Participant without access to the Information of the Disclosing Participant.

- h. In addition, the Receiving Participant shall be permitted to disclose Information received hereunder as may be strictly required by order of competent legislative or judicial authorities to which is it directly subject, provided that the Receiving Participant shall:
 - i. immediately notify the Disclosing Participant in writing of any effort made to obtain Information of the Disclosing Participant by such order, and provide adequate opportunity to the Disclosing Participant to object to, or restrict, such disclosure or request confidential treatment thereof; and
 - ii. take all reasonable measures in an effort to ensure that the Information in question will be disclosed to such competent legislative or judicial authorities in a manner that protects such Information from public disclosure (provided always, however, that nothing contained in this paragraph h shall be construed as a waiver of the privileges and immunities enjoyed by WHO and/or to submit WHO to any national court jurisdiction).

- i. Upon completion of the Purpose and in the absence of any further written agreement between the Participants, each Participant shall cease all use, shall make no further use of the Information disclosed to it hereunder, and shall, upon written request from the other Participant, promptly return to the other Participant, or destroy, all of the Information received from the other Participant, except that each Participant may retain one copy of the Information in its confidential files to determine any continuing obligations hereunder.
- j. Any notice to be given under this Arrangement shall be deemed to be sufficiently given for all purposes if successfully transmitted by facsimile and confirmed by mail, or if sent by registered mail or recorded delivery post (postage prepaid) addressed to the Participant to be notified at the following address:

WHO/EMP:

World Health Organization
Director, Department of Essential Medicines and Health Products
20 Avenue Appia
1211 Geneva 27
Switzerland
Tel. + 41 22 791 3632
Fax. + 41 22 791 4167

FDA:

Associate Commissioner for International Programs
Office of International Programs
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States of America
Tel. + 1 301 796 4600
Fax. + 1 301 595 7937

- k. This Arrangement constitutes the entire understanding of the Participants hereto with respect to the subject matter hereof and shall not be modified except by mutual agreement in writing.
- l. This Arrangement shall not in any way affect any prior arrangements between FDA and WHO, including any subdivision of WHO, relating to the disclosure

of different information (other than the Information) for a different purpose (other than the Purpose).

- m. The Receiving Participant will promptly inform the Disclosing Participant of any circumstances or changes that would affect its ability to honour the commitments in this Arrangement.
- n. Nothing in or relating to this Arrangement shall imply an obligation on the part of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO under any national or international law, convention or agreement.
- o. In the unlikely event that any difference shall arise in the interpretation or application of this Arrangement, the matter shall be submitted to the Director of the Office of Global Health Affairs within the U.S. Department of Health and Human Services and to the Assistant Director-General responsible for General Management of the World Health Organization, who will settle the question personally and jointly or through their duly authorized representatives.

Signed on Behalf of FDA

_____/S/_____
Name: Dara A. Corrigan

Title: Acting Deputy Commissioner for Global Regulatory Operations and Policy
United States Food and Drug Administration

Date:

Signed on Behalf of WHO/EMP

_____/S/_____
Name: Dr. Suzanne Hill

Title: Director, Department of Essential Medicines and Health Products
World Health Organization

Date: 8-31-17