*[SPONSOR SHOULD PREPARE ON ITS LETTERHEAD]*

**SPONSOR'S AUTHORIZATION**

**FOR FDA TO SHARE CONFIDENTIAL COMMERCIAL AND/OR TRADE SECRET INFORMATION WITH THE WORLD HEALTH ORGANIZATION’S**  **REGULATION OF MEDICINES AND OTHER HEALTH TECHNOLOGIES UNIT AND**

**TO POST CERTAIN INFORMATION ON FDA AND WHO WEBSITES**

Date: Day, Month, Year

Office of Global Policy and Strategy

United States Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

RE: United States Food and Drug Administration’s (FDA’s) Sharing of Certain Non-Public Information concerning [Company]’s PEPFAR Applications (as defined below) with the World Health Organization’s (WHO’s) Regulation of Medicines and Other Health Technologies Unit and the Subsequent Posting of Certain Information concerning PEPFAR Applications on FDA’s and WHO’s Public Websites.

Dear FDA Official:

I. On behalf of [Company], I authorize the United States Food and Drug

Administration (FDA) to share all information on PEPFAR Applications[[1]](#footnote-1) and the products contained therein, that [Company] has submitted, or will submit, for review under the President's Emergency Plan for AIDS Relief (PEPFAR) Program with theWorld Health Organization Regulation of Medicines and Other Health Technologies Unit (WHO/RHT) solely for the purpose of undertaking discussions aimed at coordinating and facilitating FDA’s regulatory activities and support of WHO/RHT’s pre-qualification activities. I understand that the information to be shared may contain trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331(j), and 5 U.S.C. § 552(b)(4) that are exempt from public disclosure. I also understand that this Authorization covers all PEPFAR Applications, so that a new authorization to share information need not be generated for future PEPFAR Applications.

II. In addition, on behalf of [Company], for each PEPFAR Application specified under this Authorization Letter, I consent to FDA’s placing the following information on FDA’s publicly available website and sharing this information with the WHO for posting on its website at the time of a decision action i.e., approval, tentative approval, or permitted of the PEPFAR Application:

1. Application Number
2. Established Name
3. Strength
4. Dosage Form
5. Applicant
6. Drug Product and Drug Substance Manufacturing Sites (name and address only)
7. Packaging Material and Pack
8. Drug Labeling Information
9. Drug Product Shelf-Life
10. Storage Conditions
11. Certain Permitted Changes[[2]](#footnote-2)

[Company] retains the right to specify for any individual PEPFAR Application that [Company] does not wish the information to be shared with WHO or be placed on FDA’s and WHO’s public websites and can provide a statement to that effect to FDA at the time of a decision action. [Company] agrees to hold FDA harmless for any injury caused by FDA's sharing the information withWHO/RHT.

Authorization is given to FDA to take the above-mentioned actions in Sections I, with regards to information related to [Company]’s PEPFAR Applications as specified without deleting trade secret information. FDA may also, on its public website, post this signed Sponsor Authorization Letter.

As indicated by my signature, I am authorized to provide this consent on behalf of [Company] and my full name, title, address, telephone number, and facsimile number are set out below for verification. I am sending a copy of this letter to WHO/RHT. I give this consent with the understanding that such information might constitute confidential commercial or trade secret information entitled to protection from public disclosure under FDA regulations, including 21 CFR 20.61 and 21 CFR 314.430, and I waive that protection.

Sincerely,

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(Signature)

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(Printed name)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Title)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Telephone & Fax Numbers)

cc: World Health Organization Regulation of Medicines and Other Health Technologies Unit

1. PEPFAR Applications include the following types of applications: (i) original new drug applications (NDAs) and abbreviated new drug applications (ANDAs) that have received FDA tentative approval; (ii) NDAs and ANDAs that have received FDA tentative approval, and which have been amended to reflect certain changes that have subsequently been permitted by FDA; (iii) original NDAs and ANDAs that have received FDA approval; and (iv) supplements to NDAs and ANDAs that have received FDA approval. PEPFAR Applications also include any of the applications identified in (i) to (iv) that were not submitted under the PEPFAR Program, but whose sponsors have requested the United States Food and Drug Administration (FDA) to list the applications on the FDA PEPFAR list of antiretrovirals (ARVs) and have met FDA’s requirements for the submission of stability data to support use in countries with hot and dry or hot and humid conditions. [↑](#footnote-ref-1)
2. Refers to changes submitted as amendments to applications that have received FDA tentative approval and for which FDA has subsequently issued a PEPFAR Permitted Letter. [↑](#footnote-ref-2)