**MODEL OWNER’S**

**AUTHORIZATION FOR FDA TO SHARE**

**CONFIDENTIAL COMMERCIAL AND/OR TRADE SECRET INFORMATION WITH A FOREIGN GOVERNMENT AGENCY OR INTERNATIONAL ORGANIZATION**

*(OWNER OF THE NON-PUBLIC INFORMATION SHOULD PREPARE ON ITS LETTERHEAD)*

*[DATE]*

*[FDA Component contact name]*

*[Title]*

*[Office]*

*[Center]*

U. S. Food and Drug Administration

*[Address]*

RE: FDA’s Sharing of Non-Public Information concerning *[Insert Application Number, Insert Name of Regulated Product(s)]* with *[Insert name of Foreign Government Agency or International Organization]*

Dear *[Component contact]*,

On behalf of *[insert name of owner of the information]*, the owner of trade secret information related to the above-referenced regulated product(s), I authorize the United States Food and Drug Administration (FDA) to share the information described below with the *[insert name of Foreign Government Agency or International Organization]* solely for the purpose of *[insert description of purpose].* I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 5 U.S.C. § 552(b)(4), 21 U.S.C. § 306j(c), and 21 U.S.C. § 387f(c) that is exempt from public disclosure.

I agree to hold FDA harmless for any injury caused by FDA's sharing the information with *[insert name of Foreign Government Agency or International Organization]*.

Information to be shared: Any data or information regarding *[NDA or BLA or supplement #]:*

Authorization is given to FDA to share the above-mentioned information without deleting confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of *[insert name of company]* and my full name, title, address, telephone number, and fax number are set out below for verification. I am sending a copy of this letter to *[the Foreign Government Agency or International Organization]* with which FDA may share the information.

Sincerely,

(Signature)

(Printed name)

(Title)

(Telephone & Fax Numbers)

cc: *[insert NDA, BLA or supplement #*]

cc: *[Name of Foreign Government Agency Contact or International Organization]*