

EXHIBIT B

MODEL AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH THE DEPARTMENT OF DEFENSE

[To be completed on applicant/sponsor/information-owner letterhead]

[FDA Official – e.g., Center or Office Director]

United States Food and Drug Administration

10903 New Hampshire Avenue

Building __, Room ____

Silver Spring, MD 20993

[Identify relevant FDA Tracking number – e.g., NDA/ANDA/BLA, EUA/Pre-EUA, master file, etc.]

Re: FDA Sharing of Non-Public Information Concerning *[insert name of regulated product(s)]* with Department of Defense (DoD) Partners²

On behalf of *[insert name of information owner]*, I authorize the United States Food and Drug Administration (FDA) to share with DoD Partners, and with contractors to those Partners, all information concerning the above described product(s) that *[insert name of information owner]* has provided or will provide to FDA or to any other DoD Partner. I understand that those Partners have committed to use such information only for the purposes of the DoD and have committed or are otherwise legally required to maintain the confidentiality of such information (or both), and that contractors to DoD are bound by their contracts to maintain the confidentiality of the information. I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 USC § 1905, 21 USC § 331(j), and 5 USC § 552(b)(4), that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosure of this information.

Authorization is given to FDA to share this information without deleting confidential commercial or financial or trade secret information. This authorization shall remain valid unless revoked in writing. As indicated by my signature, I am authorized to provide this consent on

² DoD Partners include the U.S. Army Medical Research and Materiel Command (USAMRMC), the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Joint Science and Technology Office (JSTO) of the Defense Threat Reduction Agency (DTRA), the Defense Advanced Research Projects Agency (DARPA), and other DoD entities.

behalf of [*insert name of information owner*] and my full name, title, address, telephone number, and facsimile number are set out below for verification.

Sincerely,

(Signature)

(Printed name)

(Title)

(Address)

(Telephone & Facsimile Numbers)

cc:

Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist, FDA
(EUA.OCET@fda.hhs.gov)

The primary MCM Center, as follows:

For CBER, (Counterterrorism and Medical Countermeasures Staff or CBEREUA@fda.hhs.gov)

For CDER, (Counter-Terrorism and Emergency Coordination Staff or CDEREUA@fda.hhs.gov)

For CDRH, for IVD medical devices, (device@fda.hhs.gov) and for non-IVD medical devices
(cdrhemcm@fda.hhs.gov)