

MEMORANDUM OF UNDERSTANDING CONCERNING
COORDINATION WITH THE FOOD AND DRUG ADMINISTRATION
REGARDING DEPARTMENT OF DEFENSE
MEDICAL PRODUCT DEVELOPMENT AND ASSESSMENT

PREAMBLE

On December 12, 2017, the President signed into law Public Law No. 115-92 (P.L. 115-92), an Act to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by biological, chemical, radiological or nuclear (CBRN) agents or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces and for other purposes. P.L. 115-92 requires enhanced collaborations and communication between the U.S. Department of Defense (DoD) and the U.S. Food and Drug Administration (FDA) on DoD's medical product priorities (MPPs) for military emergencies. This Memorandum of Understanding (MOU) implements the framework for this Congressionally-directed collaboration between DoD and FDA (collectively, "the Parties").

I. PURPOSE

To implement P.L. 115-92 through an efficient collaboration between DoD and FDA in order to:

- a. Facilitate access to medical products for use during military emergencies (or the significant potential for a military emergency) involving a heightened risk to the U.S. military forces of an attack with a CBRN agent or other agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces;
- b. Facilitate, through enhanced engagements, DoD's development of promising safe and effective medical products that are reasonably likely to address a life-threatening military emergency (or significant potential for a military emergency), involving a specific and imminently life-threatening risk to United States military forces of attack;
- c. Plan and conduct *semi-annual* meetings between senior DoD and FDA leadership to facilitate enhanced collaboration and communication on DoD MPPs that are the highest priorities to DoD;
- d. Plan and conduct *quarterly* meetings between the Director of FDA's Center for Biologics Evaluation and Research (CBER) and the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to facilitate enhanced collaboration and communication on regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to DoD;
- e. Facilitate communication of information relating to the safety, efficacy, and utilization of medical products in the DoD portfolio;

- f. Further enhance efforts to share information and expertise through more efficient and robust inter-agency activities;
- g. Facilitate DoD's identification, development, and application of enabling scientific tools, technologies, and regulatory science approaches that will support the timely availability of useful medical products to address the unique healthcare needs of military personnel;
- h. Clarify the DoD's actions necessary to support timely development of DoD MPPs;
- i. Clarify FDA requirements applicable to MPPs that are being sponsored or otherwise supported or needed by DoD; and
- j. Maintain appropriate, robust information and data security standards and practices.

II. AUTHORITY

FDA has authority to enter into this MOU pursuant to sections 1003(b) and (c) of the FD&C Act (21 USC §§ 393(b) and (c)).

DoD has authority to enter into this MOU under DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013; DoD Directive 6200.04, "Force Health Protection," October 9, 2004; DoD Instruction 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs," February 27, 2008; and DoD Instruction 4000.19, "Support Agreements," April 25, 2013.

III. BACKGROUND

DoD and FDA have collaborated on medical product development priorities to treat the unique needs of the warfighter since the original 1964 MOU between the Parties. It is DoD's long-standing policy to: (a) provide military personnel the best possible healthcare, including safe and effective medical products to address CBRN warfare, endemic disease, battlefield trauma and injury, and other conditions; and (b) to make preferential use of products approved by the FDA for commercial marketing, when available, to provide the needed medical countermeasure and treatment. FDA ensures that such medical products are safe and effective for their intended use. Product-specific regulatory review is conducted within FDA medical product Center divisions with additional support from Center specialized medical countermeasure experts. In addition, the Centers and FDA's Office of Counterterrorism and Emerging Threats (OCET) have met with stakeholders across the DoD medical product development enterprise, including 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 others.

Increased DoD-FDA collaboration was addressed in the National Defense Authorization Act for Fiscal Year 2018 (*see, e.g.*, §716 of P.L. 115-91), leading to the enactment of P.L. 115-92 (Dec. 12, 2017). This law amended the FD&C Act to provide, among other things, specific policy for increased DoD-FDA collaboration on the development and availability of MPPs. In summary, P.L. 115-92:

- a. Expands FDA's emergency use authorization (EUA) authority under §564 of the FD&C Act to allow FDA to issue EUAs for emergency use of unapproved medical products or unapproved uses of approved medical products to address additional types of threats (beyond CBRN agents) related to attack with an "agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the United States military forces" (*see* §1(a), P.L. 115-92);
- b. Allows the Secretary of Defense to request, and authorizes FDA to take, specific actions to expedite the development of medical products, and the review of investigational submissions, applications for approval/licensure, and submissions/notifications for clearance for such medical products reasonably likely to diagnose, prevent, treat, or mitigate a specific and life-threatening risk to the U.S. military (*see* §1(b), P.L. 115-92); and
- c. Requires semi-annual review between DoD and FDA on DoD's MPP portfolio and requires quarterly DoD-CBER meetings for CBER-regulated MPPs (*see* §1(b)(3), P.L. 115-92).

In addition, discussions among representatives of the Parties to further these purposes may involve trade secret, commercial confidential, or other non-public information. Participation in such discussions also requires avoiding the appearance of impropriety or conflicts of interests by participants. This MOU governs how the Parties will address these issues.

IV. AGREEMENT

In order to accomplish the purposes articulated above, the Parties agree to the following:

a. Points of Contact.

Each Party will establish a principal point of contact (POC) to facilitate the actions carried out under this MOU.

b. Framework for DoD-FDA Collaboration.

1. Development and Maintenance of the DoD Priority List.
 - a. DoD will develop and maintain a DoD MPP List (the Priority List).
 - b. The Priority List is intended to reflect the DoD-wide view on the most important and urgent medical product needs of military personnel that require increased interaction with FDA or elevation to the appropriate FDA Center Director and/or FDA Commissioner, as needed, consistent with the intent of P.L. 115-92.
 - c. The Priority List will be categorized by MPPs for which the DoD:
 - i. Anticipates it may seek emergency use under an appropriate emergency access mechanism, including EUA;
 - ii. Requests FDA to take action to expedite the development of such medical products, and the review of investigational submissions, applications for approval/licensure, and submissions/notifications for clearance of such medical products reasonably likely to diagnose, prevent, treat, or mitigate

- a specific and life-threatening risk to the U.S. military, including those for which emergency access is needed; or
 - iii. Seeks assistance in resolving a cross-cutting matter of regulatory science or policy.
- d. The Priority List will provide for each listed MPP information substantially similar in content and format to **Exhibit A**, Model DoD Priority List Elements, including current regulatory applicant/sponsor information. The MPPs will be ranked by their priority and the Priority List may be expressed in a “1-n” format, by adjectival ratings, and/or be organized by the FDA center of jurisdiction as the Parties deem appropriate.
- e. While the DoD is the regulatory applicant/sponsor for many of its medical product development programs, the Parties acknowledge that for many DoD MPPs, the regulatory applicants/sponsors are non-governmental entities for which the product development is DoD-supported by a contract under 10 USC §2304 and §2358, other transaction authority (OTA) under 10 USC §2371a or §2371b; by a cooperative research and development agreement (CRADA) under 15 USC §3710a; by a grant or cooperative agreement under 10 USC §2358; or by an interagency agreement with another government agency under the Economy Act, 31 USC §1535; or alternatively, a memorandum of agreement (MOA). The Parties acknowledge that emergent issues could result in a product being placed on the Priority List without a pre-existing relationship between the applicant/sponsor and the DoD or when DoD’s relationship with the applicant/sponsor is secondary to another federal government product developer (e.g., HHS Biomedical Advanced Research and Development Authority (BARDA)). When the regulatory applicant/sponsor of a product on the Priority List is a non-governmental entity, DoD will ensure that any information shared about that product is within DoD authority to share and/or such rights to disclose the information to FDA are obtained before disclosure. FDA will also require permission of the owner of such information before any disclosure is made to DoD and, accordingly, such permission may be granted to FDA using terms such as those contained within the model authorization at **Exhibit B**. When the regulatory applicant/sponsor of a product on the Priority List is a non-DoD governmental entity (e.g., BARDA), disclosure may be facilitated using other existing MOUs, such as under the terms of the Public Health Emergency Medical Countermeasure Enterprise MOU.¹
- f. DoD will update the Priority List, as needed, prior to each semi-annual and quarterly FDA meeting outlined in this section.

2. Semi-Annual DoD meeting with FDA.

- a. The Parties agree that there will be at least a semi-annual meeting between the ASD(HA) and FDA Senior leadership, coordinated through the Office of the Commissioner (e.g., OCET), ensuring participation of the Directors of the Center for Drug Evaluation and Research (CDER), CBER, and the Center for Devices

¹ MOU 225-13-013, see FDA website at:

<https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm402857.htm>.

- and Radiological Health (CDRH), or their designees, with any other participation as appropriate based on the MPPs listed on the Priority List (e.g., DoD and/or FDA subject matter experts, other development partners, such as BARDA).
- b. The Priority List will be presented to FDA two-weeks in advance of each meeting to allow FDA to prepare for the discussion.
 - c. The Priority List will be presented to FDA in a manner that facilitates FDA's understanding of the products' intended use; context of use; the urgency of the need (as it relates to both the risk to military forces and the capability gaps to respond, and whether emergency use is anticipated); and what is known about the product(s), including but not limited to the formulation, route of administration, dosage form, active ingredients, and available data related to the products' safety and effectiveness. A format substantially similar in content and format to **Exhibit A**, Model DoD Priority List Elements, will facilitate this understanding.
 - d. The semi-annual meetings are for the express purpose of presenting and discussing the Priority List with FDA and do not limit or replace ongoing meetings for routine military medical product development efforts or other regulatory activity.
3. Quarterly DoD meeting with FDA CBER.
- a. The Parties agree that there will be a quarterly meeting between DoD and the Director of CBER.
 - b. DoD will present those regenerative medicine advanced therapy, blood, and vaccine medical products that are on the Priority List.
 - c. When there are combination products on the Priority List, some of which contain constituent parts that are subject to CDER's, CDRH's, or another FDA Center's jurisdiction, CBER will coordinate the participation of the other FDA Center when such input may be helpful.
 - d. The Quarterly CBER meetings are for the express purpose of presenting and discussing the CBER-regulated medical products on the Priority List and do not limit or replace ongoing meetings for routine military medical product development efforts or other regulatory activity.
4. Collaborations to Facilitate Emergency Use of Medical Products.
- a. FDA agrees to facilitate DoD's ability to field, when necessary, investigational medical products under a clinical trial if appropriate and feasible, under an expanded access mechanism, or under an EUA, and to assist DoD in determining the appropriate course of action among or between these non-exclusive approaches;
 - b. Discussions related to appropriate regulatory mechanisms for emergency uses of MPPs on the Priority List will be a part of each of the meetings described in Section 2 and 3 above.
5. Enhanced Engagements to Facilitate the Development of DoD MPPs.
- a. FDA agrees to coordinate requests by the DoD to expedite the development of MPPs and the review of investigational submissions, applications for approval/licensure, and submissions/notifications for clearance of such medical

products reasonably likely to address a life-threatening military emergency (or significant potential for a military emergency) involving a specific and imminently life-threatening risk to United States military forces;

- b. The Parties will discuss the application of the FDA and DoD actions to expedite the development and review of medical products on the Priority List set forth in §(b)(2) of P.L. 115-92, including but not limited to:
 - i. Holding meetings with the applicant/sponsor (with necessary parties included to ensure meeting productivity) and the FDA review team throughout the MPP's development;
 - ii. Providing timely advice and interactive communication regarding the development of the MPP to ensure that the development program to gather the nonclinical and clinical data needed for approval or clearance is as efficient as practicable;
 - iii. Assigning a cross-disciplinary project lead for the FDA review team to facilitate efficient review of the MPP's development program and communications with the applicant/sponsor;
 - iv. Taking steps to ensure the clinical trial design is as efficient as practicable and that assessment of risk and benefit are relevant to the proposed context of use;
 - v. Applying any applicable programs to expedite the development and review of the DoD MPP application (See e.g., *Expedited Programs for Serious Conditions—Drugs and Biologics*, May 2014); and
 - vi. Discussing the appropriateness of an expanded access mechanism. (See e.g., *Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers*, June 2016 updated October 2017).
 - c. As needed, such coordination will be a part of each of the meetings described in Section 2 and 3 above.
6. Consideration of Priority Cross-Cutting Regulatory Science Issues.
 - a. The Parties agree to discuss DoD's cross-cutting regulatory science and policy issues that, if resolved, could accelerate development of multiple products in the DoD medical product portfolio as intended by P.L. 115-92.
 - b. The Parties agree that discussion of a regulatory science or policy issue may, but is not required to, relate to a product or product(s) on the Priority List.
 7. MOU-Related Procedures.
 - a. Each Party agrees to attend an initial meeting to establish specific procedures and safeguards necessary to implement this MOU. The initial meeting will take place as soon as possible after the signing and approval of this MOU.
 - b. Periodic meetings will be scheduled thereafter consistent with the terms of Section IV above.

V. CONFIDENTIALITY OF INFORMATION

1. All Parties recognize and acknowledge that information exchanged with FDA that contains any of the following types of information must be protected from unauthorized

use and disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 USC §1905)), the Privacy Act (5 USC §552a), other FOIA exemptions not mentioned above (5 USC §552(b)), the FD&C Act (21 USC §301 *et seq.*), as amended, the Health Insurance Portability and Accountability Act (HIPAA), P.L. 104-191), Section 319L(e) of the Public Health Service (PHS) Act (42 USC § 247d-7e(e)), and disclosure restrictions subject to 41 USC 2101-2107 (Procurement Integrity Act) and 48 CFR 3.104 (Federal Acquisition Regulation). Additionally, all federal agencies and contractors supporting them are under the Federal Information Security Management Act (FISMA), E-Government Act of 2002 (P.L. 107-347, 116 Stat. 2899, 44 USC § 3541 *et seq.*). Pursuant to section 301(j) of the FD&C Act (21 USC 331(j)), the FDA will not reveal to DoD representatives information entitled to protection as a trade secret unless there is in place a written authorization from the owner of that information that permits the FDA to reveal such information to representatives of DoD. Such authorization may be obtained by having the owner of that information submit the authorization to the FDA with terms similar to the model authorization in **Exhibit B**.

2. In addition, DoD will ensure that any classified (e.g., Secret or Top Secret) information provided to the FDA is done so consistent with the authorities applicable to the control of such information, including but not limited to Executive Order (EO) 13526, Classified National Security Information. Should the Parties need to discuss any classified information pertaining to a DoD medical priority or risk, the Parties will utilize a secure room supplied for that purpose. Parties will ensure that all classified information is handled with extreme care and consistent with applicable rules and procedures.
3. Each Party will establish proper safeguards to ensure that information shared under this MOU shall be used and disclosed solely in accordance with applicable laws and regulations. Access to such information shared under this MOU shall be restricted to authorized FDA and DoD employees, agents, and officials who require access to perform their official duties in accordance with the uses of information as authorized by this MOU. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information; and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws.
4. Contractors, their subcontractors, and agents requiring access to the information shared under this MOU will be required to sign an agreement by which they will commit to keep the information confidential.
5. DoD and FDA agree to promptly notify each other of any actual or suspected unauthorized disclosure of information shared under this MOU. Each Party is similarly

under an affirmative obligation to report breaches of Personally Identifiable Information (PII), which might include Protected Health Information (PHI), or Individually Identifiable Health Information (IIHI), under appropriate authorities and time frames, such as FISMA, HIPAA, and the Privacy and Health Information Technology for Economic and Clinical Health (HITECH) Acts.

6. If a Party that has received information shared under this MOU receives a FOIA request for information shared by the other Party pursuant to this MOU, the receiving Party will refer the request to the information-sharing Party for that agency to respond directly to the requestor regarding whether or not the release of the information at issue is permissible. In such cases, the Party making the referral will notify the requestor that a referral has been made and that a response will be issued directly from the other agency.
7. Each Party agrees that it may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise shared in response to a particular request. A decision not to share information in response to a specific request may be based on several factors, including, for example, the amount of resources necessary to fulfill the request, the reasonableness of the request, DoD's unique national security priorities, or legal restrictions. There is, however, agreement to share information to the maximum extent possible in furtherance of the purposes of this MOU. The Parties further agree that a Party may on its own initiative elect to share information pursuant to procedures established above to further the purposes of this MOU. In the event the Parties cannot reach consensus on a decision to share or not share information, the issue will be referred to the signatories of this MOU, or their successors, for resolution.
8. The Parties further agree that nothing in this MOU shall be construed to prevent a disclosure required by law or legal process. Notwithstanding this provision, should information shared pursuant to this MOU be subpoenaed or otherwise ordered through a legal process, the Party to whom the subpoena or order is directed will immediately notify a Liaison Officer of the other Party that shared the information to provide an opportunity to seek to intervene and block the disclosure. This MOU does not prohibit disclosure of information that is available publicly or when authorized in writing by the information owner.
9. The Parties agree that termination of this MOU does not relieve them of their confidentiality obligations established under this MOU, including their obligations to safeguard and limit access to all information provided pursuant to this MOU.

VI. CONFLICTS OF INTEREST

1. Executive Order 12674, Standards of Ethical Conduct for Employees of the Executive Branch, and individual agencies' standards of conduct contain rules and regulations that govern the ethical obligations applicable to Government employees. Federal law generally prohibits a Federal employee from participating personally and substantially in any particular matter in which the employee has a financial interest (18 U.S.C. §208).

The restriction also applies to financial interests of an employee's spouse; minor child; partner; organization in which he or she is serving as officer, director, trustee, partner or employee; and any person or organization with whom the employee is negotiating or has any arrangement concerning prospective employment. Ethics requirements applicable to Federal personnel also broadly prohibit employees from engaging in a financial transaction using nonpublic information and prohibit the improper use of nonpublic information to further his or her own private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure. In addition, HHS Supplemental Standards of Ethical Conduct impose additional conditions, such as unique prohibited-holdings regulations for certain FDA personnel.

2. Representatives to any discussion under this MOU must not have a prohibited financial conflict of interest through personal or family investments in an applicant /sponsor/owner of information contained in a master file, or a competitor to the applicant/sponsor/information-owner, who will be affected by FDA decisions. If at any time prior to or during the performance of activities under this MOU, a person becomes aware that a potential or actual conflict exists, that person must notify the appropriate authorities within his or her own agency, including the designated liaison officers listed in this MOU.

VII. INTEGRITY OF THE REGULATORY DECISION-MAKING PROCESS

FDA participation is predicated on a mutual understanding that DoD-FDA meetings under this MOU provide a forum for a mutual exchange of opinions and ideas, and that DoD-FDA meetings must avoid any appearance that procurement or investment considerations may influence FDA regulatory decision-making concerning product licensure, clearance, approval or authorization. FDA employees generally will not participate in discussions or decision-making regarding the terms of procurement of or investment in a medical product. FDA representatives may participate in discussions under this MOU to provide FDA's current thinking on scientific or regulatory issues within FDA's areas of responsibility and expertise.

VIII. GENERAL PROVISIONS

This is an internal government agreement between the Parties to this MOU and does not confer any rights or benefits to any person or party. This MOU does not include any commitment, by any Party, of resource contributions or exchanges.

This MOU does not supersede any existing agreements or arrangements between the Parties; to the extent the provisions of this MOU conflict with any existing or future agreement between DoD and FDA, the provisions of this MOU shall govern FDA communications relating to DoD MPPs. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Parties operate, and nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by any Party. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on any Party that is additional to the mandates or requirements imposed on them, individually or collectively, by Federal statutes and regulations.

IX. LIAISON OFFICERS

The following designations of liaison officers are by position. Subsequent occupants of those positions are deemed to assume the roles of liaison officers for purposes of this MOU.

For the Food and Drug Administration:

Mr. Michael Mair
Director (Acting), Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Michael.mair@fda.hhs.gov
301-796-0738

For the Department of Defense:

Dr. Terry M. Rauch
Acting Deputy Assistant Secretary of Defense
for Health Readiness Policy and Oversight (HRP&O)
Office of the Assistant Secretary of Defense
for Health Affairs (ASD[HA])
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101
terry.m.rauch.civ@mail.mil
(703) 681-8472

X. DISPUTES

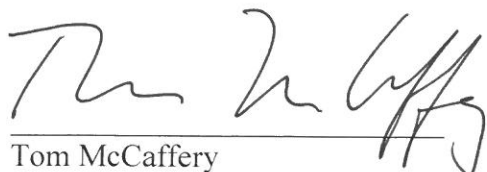
Any disputes relating to this MOU will, subject to any applicable law, executive order, directive or instruction, be resolved by consultation between the Parties or in accordance with DoD Instruction 4000.19, "Support Agreements."

XI. TERM, TERMINATION AND MODIFICATION

This agreement will be effective as to a participating Party when accepted by that Party and remain in effect unless terminated or superseded. This agreement may be modified or terminated by mutual written consent of the Parties or may be terminated by either Party upon a 60 day advance written notice to the other Party.

XII. SIGNATURES

The undersigned are authorized to and hereby agree to the foregoing MOU on this second day of November, 2018, in Fort Detrick, Maryland:



Tom McCaffery
Principal Deputy Assistant Secretary
of Defense for Health Affairs



Scott Gottlieb, M.D.
Commissioner of Food and Drugs

EXHIBIT A
MODEL DOD PRIORITY LIST DATA ELEMENTS

DoD Medical Product Priorities (MPPs)								
FDA Tracking Number (a)	Product Name (b)	Applicant/Sponsor (c)	Proposed Indication/Use (d)	Regulatory Status (e)	FDA Review Office/Division (f)	DoD Lead (g)	DoD Priority Rank (e.g., # out of #) (h)	Notes (i)
CBER Regulated								
CDER Regulated								
CDRH Regulated								

- a. **FDA Tracking Number** – As applicable (e.g., Pre-IND#, IND#, Pre-EUA#, EUA#, NDA#, ANDA#, BLA#, PMA#, 510K#, Q# etc.)
- b. **Product Name** – List current name of the product and any other names previously used (e.g., established name, proprietary name, etc.)
- c. **Applicant/Sponsor** – Holder of the application (application types include, but are not limited to, Pre-IND, IND, Pre-EUA, EUA, NDA, ANDA, BLA, PMA, 510K, etc.)
- d. **Proposed Indication** – The intended use of the product, including population and/or operational considerations (note here elements including but not limited to the formulation, route of administration, dosage form, active ingredients, and available data related to the products' safety and effectiveness, and whether the product is a supplemental change to already approved application or modification to already cleared device)
- e. **Regulatory Status** – Regulatory status of the product (e.g., pre-IND, IND, Inactive, IDE, pre-EUA, EUA, Approved, Licensed, Cleared, etc.)
- f. **FDA Review Office/Division** – FDA review division with primary responsibility for review of the product (also list FDA project manager if applicable)
- g. **DoD Lead** – DoD office/command/program/component (e.g., MRMC, MCS, etc.) developing or supporting the product's development and any relevant contractor organizations
- h. **DoD Priority Rank** -

- i. DoD will evaluate and rank MPPs based on need (i.e., risk-to-mission of an unmet medical need and/or capability gap) and feasibility (i.e., is the product mature enough in the development pathway and capable of deployment to offer a significant improvement over current medical treatments), as well as describe whether the MPP will require emergency use, accelerated management, or whether there is a cross-cutting regulatory science issue or some combination thereof.
 1. DoD will provide a rank order (1-n) for the MPPs on the Priority List based on the need and feasibility and the ratings applied to the MPP.
 2. The Priority List may be presented in a both a “1-n” manner, based on the FDA Center with jurisdiction (CDER, CBER, or CDRH), or some combination thereof at the discretion of the Parties.
 3. While DoD will independently rank its MPPs on the Priority List, the Parties acknowledge that FDA’s input on the Priority List is valuable. Accordingly, the Parties may agree to place an additional adjectival rating on the DoD-presented Priority List if necessary (e.g., “Top,” “High” or “Elevated,” etc.).
- i. **Notes** - Any additional information that, if available, is deemed useful (e.g., whether the product is a combination product; ongoing product development coordination with another US Government agency, such as BARDA; whether DOD Advanced Development Manufacturing Facility (ADM) or manufacturing outside the U.S. and fill/finish of the product will occur).

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)