Food and Drug Administration
Initial Work Plan for Products Relevant to the Department of Defense (DoD)
January 2018

By adopting important amendments to section 564 of the Federal Food, Drug, and Cosmetic Act under H.R 4374 [Public Law No: 115-92], Congress provided the Food and Drug Administration (FDA or the Agency) with a new framework and tools to prioritize the efficient development and availability of medical products intended to help save the lives of American military personnel on the battlefield.

Since December, the FDA has been working closely with the Department of Defense (DoD) on a plan to implement the provisions recently enacted by Congress. Our aim is to create a robust and enduring pathway that will efficiently address the needs of the DoD and meet the Agency's obligations to our military service members. FDA's leadership is deeply committed to this effort. It is one of the Agency's highest priorities to both deliver and potentially expand upon the intent of these new provisions.

Given that DoD's most pressing medical product needs fall within FDA's Center for Biologics Evaluation and Research (CBER), DoD and FDA have agreed that products regulated by CBER will be the initial priority focus for implementing these new commitments. Under this new approach, FDA will facilitate the development and availability of specific products regulated by CBER determined by DoD to be important to the health of those protecting our Nation.

FDA understands that DoD's priority development programs include those programs operated by the U.S. Army Medical Research and Materiel Command, the Joint Program Executive Office for Chemical and Biological Defense, the Defense Health Agency, and the Defense Advanced Research Projects Agency. DoD may also direct FDA to include additional defense operating units as appropriate. For the initial purposes of this work plan for CBER, current top priority DoD programs include freeze-dried plasma, cold-stored platelets, and cryopreserved platelets.

FDA will take the following steps to enhance collaboration and coordination with DoD's priority development programs:

1. Better understand the portfolio and developmental priorities of DoD;
2. Treat all priority DoD development programs as if they had received breakthrough designation;
3. Undertake review of prior advice to DoD and other sponsors of relevant products;
4. Provide extensive manufacturing and clinical advice for prioritized products;
5. Develop and issue guidance to facilitate the availability of products needed by DoD;
6. Maintain an open line of communication to revisit and refine priorities over time; and
7. Ensure accountability for FDA commitments to DoD.

The seven elements are explained in detail below.

FDA believes that this partnership program between CBER and DoD will ensure that those products that are prioritized by DoD as important to the health of those involved in national defense receive the highest level of attention from the Agency, on par with breakthrough designated therapies. The goal is to see safe and effective products more efficiently reach those protecting our Nation. FDA leadership is committed to ensuring that these commitments are applied to address aspects of DoD's portfolio throughout the FDA medical product centers.

Better understand the portfolio and developmental priorities of DoD

CBER leadership and subject matter experts will meet on a regular basis with the DoD program teams involved in developing products important to the health of those involved in national defense. The FDA is committed to holding such meetings quarterly, at a minimum. The discussions will focus on understanding how DoD prioritizes its different development programs and how DoD identifies those programs that need to be expedited. This way, FDA can ensure that DoD's top priority programs receive precedence from FDA, and that all programs are adequately resourced within FDA to enable the efficient development of safe and effective products.

To facilitate these goals, FDA will create three product specifications to identify levels of criticality – top priority, high priority, and routine priority. The FDA will align its regulatory resources against the products that fall into each grouping accordingly. The categorization into one of these three priority groupings will be documented along with a brief summary of the underlying rationale. This classification will be reviewed by DoD and FDA at least quarterly.

Treat all priority DoD development programs as if they had received breakthrough designation

All DoD development programs will be offered the full extent of FDA's tools that are designed to expedite the review of high priority medical needs, and improve the efficiency of DoD's development process. At a minimum, all DoD programs managed by CBER will be treated in a manner commensurate with the provisions that are currently granted to products holding breakthrough therapy designation, which confers application of all of the appropriate available expedited development programs, enhanced communication between the sponsor and FDA during product development, and senior Agency leadership involvement and oversight of the product development and application process. To the extent that current FDA resource allocations affect this plan, CBER will consult with DoD to ensure that the most important programs are being treated in an appropriately efficient manner. The CBER Center Director will closely monitor the progress of projects within CBER that are categorized at the top and high priority levels.

Undertake internal review of prior advice to DoD and other sponsors of relevant products

Close engagement by FDA's senior managers is an essential aspect of the breakthrough therapy program. This engagement has helped expedite product development and approval. Since the current DoD portfolio of products has not uniformly had the benefit of such input, CBER senior leaders will complete a review of all products determined by mutual agreement to be a top priority to DoD by June 30, 2018. The goal of this review will be to facilitate the identification and application of insights from CBER's senior management that can potentially expedite product development by streamlining developmental requirements, as appropriate.

Provide extensive manufacturing and clinical advice for prioritized products

CBER has a cadre of experts in product manufacturing and clinical development. These experts could potentially contribute specific suggestions regarding expediting the develop programs for prioritized DoD products. In many cases, we believe that those involved in product development, particularly smaller outside developers or components within DoD itself, could benefit from such experienced advice. In order to facilitate this engagement in an appropriate manner, FDA will put a firewall between the FDA staff engaged in helping a development program progress and Agency staff who is charged with reviewing the programs as part of the medical product review process. This model, which FDA has successfully used, prevents overlap and potential conflict of interest between these teams.

Develop and issue guidance to facilitate the availability of products needed by DoD

CBER intends to hold a workshop with DoD and its development partners in order to better understand the developmental capabilities of those developing products important to the health of those involved in national defense. One focus is to better understand and agree upon the types of premarket and post-approval clinical trials that could potentially be conducted.

This work will lead to the issuance of guidance on the development of products primarily, but not necessarily limited to, austere environments, which include battlefield settings and other front-line conditions experienced by members of the armed forces. The products' labeling will provide information on the benefit and risk considerations for the intended uses.

Such guidance will include information about a development pathway relevant to initial approval of products that are intended for use in austere environments. The guidance also will include information on how the approval can be expanded to the general population, when relevant. The latter is important for the ultimate availably and sustainability of the DoD medical product development enterprise.

Maintain an open line of communication to revisit and refine priorities over time

CBER will have formal meetings with DoD at least semiannually to review the DoD product development pipeline, and will meet at least quarterly to have a detailed discussion of the DoD's highest priority programs. The current high priority programs include freeze-dried plasma, cold-stored platelets, and cryopreserved platelets. In addition, CBER Leadership will maintain an open line of communication with relevant contacts at DoD in order to receive feedback on how interactions between the agencies are proceeding and to ensure that any necessary revision of developmental priorities takes place as soon as possible. Should any concerns or urgent issues arise, DoD leadership can directly contact the CBER Center Director.

Ensure accountability for FDA commitments to DoD

The Center Director of CBER will brief the FDA Commissioner quarterly in writing regarding the ongoing activities to ensure the timely development and approval of products of importance to DoD. A general summary of activities also will be prepared and available for review that excludes commercial, confidential, and trade secret information, such as the number of products in various stages of development, meetings held, and other relevant information.

A summary of these reports will be made available every six months to the relevant House and Senate committees. FDA will make clear its commitment to DoD through a joint announcement by FDA and DoD of the action plan outlined above.