

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 6
2. AMENDMENT/MODIFICATION NO. P00001	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA 330 Independence Ave, SW, Rm G640 Washington DC 20201	CODE ASPR-BARDA02
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824		(x) 9A. AMENDMENT OF SOLICITATION NO.	9B. DATED (SEE ITEM 11)
CODE 1410445	FACILITY CODE	x 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I 75A50120F33007	10B. DATED (SEE ITEM 13) 05/24/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a)(3) - Bilateral Mutual Agreement of the Parties
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: (b) (4)
DUNS Number: 968316831

The purpose of the modification is to upgrade task order#75A50120F33007 to priority rating for Defense Priorities and Allocations System. See attachment..

Period of Performance: 05/13/2020 to 12/31/2021

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) (b) (6) (b) (6)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) CAROL C. LAVRICH	16B. UNITED STATES OF AMERICA Digitally signed by Carol C. Lavrich -S Date: 2020.08.24 12:10:01 -04'00' (Signature of Contracting Officer)	16C. DATE SIGNED 08/24/2020
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A. This is Modification No. P00001 to 75A50120F33007.

The purpose of this no cost bilateral modification P0001 is to provide notice that this is a priority DO-H5 rated task order #75A50120F33007 under Contract # HHS010020120004I with a Period of Performance 05/13/2020 to 12/31/2021 certified for national defense use.

B. Accordingly, the following changes are made to the contract:

1. Emergent Manufacturing Operations Baltimore LLC and its subcontractors at all tiers are required to follow all of the provisions of the *Defense Priorities and Allocations System regulation (15 C.F.R. part 700)* as this task order is certified for national defense and emergency preparedness use. The authority for this rating is attached (Attachment A). The priority rating issued pursuant to the authorization is subject to the restrictions in the authorization.
2. *Required Delivery Date from the Contractor:* The date for the operational readiness for the Camden facility is (b) (4) and for the Rockville facility is (b) (4).
3. The Parties agree that this change from an unrated Task Order to a DO-H5 priority rated Task Orders is a no cost change.
4. Upon execution of this modification, Emergent Manufacturing Operations Baltimore LLC and its subcontractors must give the appropriate preferential treatment to the Task Order as of the date of the modification. Emergent Manufacturing Operations Baltimore LLC shall accept, perform, and prioritize this Task Order issued under the contract.
5. The Parties agree that this modification to rate this Task Order does not significantly alter the production or delivery schedule required by the Task Order already in existence.
6. This Task Order shall take precedence over any and all other orders or contracts that do not have a priority rating and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.
7. This priority rating allows Emergent Manufacturing Operations Baltimore LLC to priority rate orders to its subcontractors and suppliers for purpose of fulfilling the priority-rated order expeditiously.
8. This priority rating automatically expires at the end of the Task Order period of performance. The parties agree that the U.S. Government (USG) may withdraw or extend this authorization at any time prior to the expiration of any Task Order period of performance at no cost to the USG.
9. If the Emergent Manufacturing Operations Baltimore LLC and/or its subcontractors are unable to comply fully with the terms of this rated order, Emergent Manufacturing Operations Baltimore LLC must immediately notify the Assistant Secretary for Preparedness and Response in writing and explain the extent to which compliance is possible and provide reasons why full compliance is not possible.

10. Emergent Manufacturing Operations Baltimore LLC agrees that the Government's right to exercise priorities and allocations authority with respect to this Task Order to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is provided. The signature, manual or digital, certifies that the rated order is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order and subcontracts by modification, if previously awarded.

C. No additional funding is incorporated into the task order under this modification.

D. All other terms and conditions remain the same.

The Parties agree that this modification includes the following documents:

Attachment Number	Title	Date
A	Request Authorization to priority rate. Emergent Manufacturing Operations Baltimore LLC. task order for "Manufacturing Capacity Reservation and Expansion" Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent Manufacturing Operations Baltimore LLC	August 17, 2020 August 19, 2020

Attachment A (3 additional pages)

REDACTED IN ITS ENTIRETY



DATE:

TO: Alex M. Azar II, Secretary

THROUGH: Ann C. Agnew, Executive Secretary

FROM: Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

SUBJECT: Request authorization to priority rate Emergent contract for industrial resources – **DECISION**

ACTION REQUESTED

This memorandum requests Secretarial approval to priority rate the Operation Warp Speed Emergent contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).

SUMMARY

As part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics, Operation Warp Speed (OWS) aims to be prepared to deliver 300 million doses of COVID-19 by January 2021, to ensure rapid scale-up, production, and delivery as soon as a safe and effective vaccine is developed. Through the direction of OWS leadership, manufacturing of vaccine components and finished vaccine products will occur in parallel with vaccine clinical development and testing. OWS implemented these concurrent work streams to speed the delivery of a safe and effective vaccine for responding to the COVID-19 pandemic since large scale bio manufacturing has traditionally had long lead times which are actively being mitigated through early activation of manufacturing.

Candidate vaccines under development as part of the OWS portfolio will be manufactured domestically within a mix of company-owned facilities, contract development and manufacturing organizations (CDMOs), and two HHS Centers for Innovation in Advanced Development and Manufacturing (CIADMs) - the Texas A&M University System (TAMUS) CIADM and the Emergent BioSolutions CIADM. Domestic manufacturing capacity for the candidate vaccines remains limited, given the number of doses required and accelerated timeframe established by OWS, as well as use of the facilities by other organizations outside the OWS portfolio that are developing COVID-19 and other vaccines. In order to prepare manufacturing facilities for commercial-scale production of a vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccines.

BARDA determined that the Emergent CIADM possesses the required experience and available capacity to be ready to manufacture Ad-vectored vaccine components at a commercial scale and within the OWS-required timeline. HHS has a contract in place with Emergent BioSolutions CIADM (Contract #HHSO100201200004I) and two relevant task orders have been awarded:

In order to prepare manufacturing facilities for commercial-scale production of a COVID-19 vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccine. DPAS priority rating is requested for vaccine pre-production activities and accelerated facilities expansion to ensure the readiness of the Emergent facility within the OWS-established timeframe by prioritizing orders for the production of BARDA- or OWS-supported vaccines or therapeutics and aiding the Contractor and its subcontractors in securing needed raw materials or equipment.

ANTICIPATED REACTION

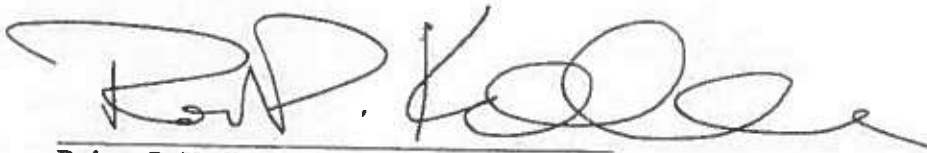
No impacts expected for other US healthcare needs (e.g., hospitals, seasonal flu response).

ROLLOUT

If approved, this request will be briefed to the Operation Warp Speed Board for review.

RECOMMENDATION

I recommend that you approve the request to priority rate the Operation Warp Speed Emergent contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).



Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

DECISION

Approved Disapproved Need More Information


Alex M. Azar II
Secretary

AUG 17 2020
Date

**Authorization to issue Defense Priorities and Allocations
System Rating for Operation Warp Speed Contract –
Emergent**

On August 19, 2020, the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) was granted, from the U.S. Department of Commerce, rating authority under the Defense Priorities and Allocations System (DPAS) regulation (15 C.F.R. part 700) for contracts and orders for “industrial resources” supporting Operation Warp Speed (OWS) projects. The U.S. Department of Commerce's Bureau of Industry and Security (DOC/BIS) authorized HHS to use the “DO-H5” priority rating on OWS contracts or orders to support private domestic production through August 31, 2022. HHS will monitor all acquisitions that carry a priority rating to ensure that each is in compliance with the DPAS regulation, and will inform DOC/BIS of any alleged violations of the DPAS of which it may become aware. HHS will also report quarterly to DOC/BIS on the contracts assigned priority ratings and their dollar value.

OWS was formed by HHS and the Department of Defense (DOD) to ramp up and expand domestic production capacity of critical health and medical resources in response to the coronavirus (COVID-19), and are funded through the Defense Production Act of 1950 (DPA) Title III authority, Coronavirus Aid, Relief, and Economic Security (CARES) Act, and/or other HHS funding sources.

Pursuant to this authority, I authorize the Contracting Officer to issue a DPAS priority rating on the Emergent BioSolutions Center for Innovation in Advanced Development and Manufacturing (CIADM) facility (“the Company”) contract for industrial resources supporting the OWS Task Orders. The order or contract issued pursuant to this authorization is subject to the following restrictions:

1. The Company shall accept, perform, and prioritize this order or contract for vaccine produced under OWS-related task orders under Contract #HHSO100201200004I in order to ensure the delivery within the OWS-established timeframe.
2. This order or contract shall take precedence over any and all orders for the Products that do not have a priority rating, and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.
3. This order or contract shall allow the Company to priority rate orders to its suppliers for purposes of fulfilling the priority-rated contracts or orders expediently.

This authorization automatically expires at the end of the contract period of performance.

Gary L.

Disbrow -S

Digitally signed by Gary L. Disbrow -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=OS, ou=People,
0.9.2342.19200300.100.1.1=20000124
25, cn=Gary L. Disbrow -S
Date: 2020.08.19 13:02:08 -04'00'

Gary L. Disbrow, Acting Director
HHS/Biomedical Advanced Research and Development Authority
Date: