

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE J	PAGE 1 OF 2
2. AMENDMENT/MODIFICATION NO. P00004		3. EFFECTIVE DATE See Blk. 16C	4. REQUISITION/PURCHASE REQ. NO. See Block 14		5. PROJECT NO. (If applicable)
6. ISSUED BY DLA TROOP SUPPORT MEDICAL SUPPLY CHAIN FSGB 700 ROBBINS AVENUE PHILADELPHIA PA 19111 USA Initiator: Phyllis Daraio PHPHAC7 Tel: 215-737-7941 FAX: 215-737-5226 Email: PHYLLIS.DARAIO@DLA.MIL		CODE SPE2D2	7. ADMINISTERED BY (If other than Item 6) DLA TROOP SUPPORT MEDICAL SUPPLY CHAIN FSGB 700 ROBBINS AVENUE PHILADELPHIA PA 19111 USA		CODE SPE2D2
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MYLAN PHARMACEUTICALS INC. 3711 COLLINS FERRY RD MORGANTOWN WV 26505-2362 USA			(X)	9A. AMENDMENT OF SOLICITATION NO.	
			X	9B. DATED (SEE ITEM 11)	
				10A. MODIFICATION OF CONTRACT/ORDER NO. SPE2D2-22-D-0145	
				10B. DATED (SEE ITEM 13) 2022 AUG 26	
CODE 3KJG9 FACILITY CODE					

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 telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter 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)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS 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 date, 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 52.212-4(c)
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

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

See Continuation Sheet

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

15A. NAME AND TITLE OF SIGNER (Type or print) Jill Dean Digitally signed by Jill Dean- jdean Date: 2023.08.21 09:45:12 -04'00'		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JASON WRAY	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)		16B. UNITED STATES OF AMERICA (Signature of Contracting Officer)	
15C. DATE SIGNED		16C. DATE SIGNED 8/22/2023	

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED: SPE2D2-22-D-0145 / P00004	PAGE 2 OF 2 PAGES
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1. This modification hereby revises Solicitation page number 24, paragraph "17. Labeling" within the Statement of Work to include Drug Supply Chain Security Act language as referenced below:

17. Labeling
 All pharmaceutical products provided under this contract shall include bar code labeling at the unit-of-use package level. The bar code labeling must be in a linear format that conforms to all GS1-128 (formerly EAN.UCC) or Health Industry Business Communication Council (HIBCC) Health Industry Bar Code (HIBC) supplier labeling standards. The bar code symbology must comply with all GS1 or HIBCC parameters including, but not limited to: symbology type or encoded pattern, bar and space dimensions and tolerances and allowable ratio of wide to narrow elements.
 The bar code may be any linear bar code symbology such as GS1-128 (formerly EAN.UCC), GS1 DataBar (formerly RSS) or Universal Product Code (if the UPC contains the National Drug Code or NDC). The bar code must encode the NDC, either alone or within the GS1 data structure (Global Trade Item Number (GTIN)). The bar code printing must be American National Standards Institute (ANSI) / International Organization for Standardization (ISO) / IEC quality grade C or better. Manufacturers and packagers must ensure that production runs include an initial verification check, as well as routine audits to ensure the bar code is printed clearly and consistently to meet the quality standard of grade C or better. Contractors shall be responsible for ensuring that bar code labels meet the quality requirements specified in this clause prior to shipping pharmaceutical products to any Government prime vendor or authorized ordering activity under this contract.
 The bar code must be on the outside container or wrapper of the medication as well as on the immediate container, unless the bar code is readily visible and machine readable through the outside container or wrapper. When the bar code is not easily machine readable through the over-wrap, the over-wrap should contain the bar code. The bar code must go on each cell of a blister pack. Furthermore, the bar code must remain intact under normal conditions of use; thus it should not be printed across the perforations of a blister pack.
 When applicable to the symbology used, bar codes shall be surrounded by sufficient quiet zone so that the bar code can be scanned correctly. Bar code placement shall minimize curvature of the bar code. For example, bar codes should be placed in "ladder orientation" on vials or bottles to minimize curvature of the bar code. Bar code labeling shall not be placed solely on outer packaging.
 It is required that bar code labeling also include the lot number and expiration date. If two separate distinctive bar codes are used, one for NDC and the other for lot number/expiration date; the lot number and expiration date bar code must not be in close proximity to the NDC barcode or in a format that may be confused with the NDC bar code. When applicable, all Healthcare Distribution Management Association (HDMA) guidelines shall be followed.

Drug Supply Chain Security Act (DCSA): The contractor shall follow all appropriate requirements as implemented in the Drug Supply Chain Security Act (DCSA), including all applicable traceability and licensing requirements.

2. All other terms and conditions remain unchanged.