

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE N/A	PAGE OF PAGES 1 3
2. AMENDMENT/MODIFICATION NO 2	3. EFFECTIVE DATE See Block 16 C	4. REQUISITION/PURC		5. PROJECT NO. (If applicable) N/A
6. ISSUED BY DHHS/ASPR/BARDA U.S. Department of Health and Human Services 330 Independence Avenue, SW, Room G640, Washington, DC 20201	CODE	7. ADMINISTERED BY (If other than Item 6)		CODE N/A
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)			(X)	9A. AMENDMENT OF SOLICITATION NO. RFP-BARDA-08-12
			X	9B. DATED (SEE ITEM 11) 2/08/2008
				10A. MODIFICATION OF CONTRACT/ ORDER NO.
				10B. DATED (SEE ITEM 13) 02/01/06
CODE	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 (1) 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 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 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.

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).
C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
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)
PURPOSE:

The purpose of this amendment is to provide answers to questions received to date in response to RFP-BARDA-08-12 entitled "Acquisition of Palatability studies for masking the respective tastes of ciprofloxacin and doxycycline when prepared for oral suspension at home during a public health emergency; and of evaluation of studies of home preparation instructions for said oral suspensions" dated February 8, 2008 which was extended to 2:00pm EST, April 7, 2008 by Amendment 1. Proposal response date remains 2:00pm EST, April 7, 2008.

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)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Darrick A. Early, Contracting Officer DHHS/BARDA	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY  (Signature of Contracting Officer)	16C. DATE SIGNED 2 April 08

Question's from Potential Offeror's for the Emergency Medical Kit (Palatability Studies)

1. It appears that the FDA website on Preparedness and Response to Bioterrorism (<http://www.fda.gov/Cder/drugprepare/default.htm>) does not currently provide draft home preparation instructions. Could you please provide the draft home preparation instructions for ciprofloxacin and doxycycline?

Answer: BARDA cannot make this information public at this time.

2. Your formulation choice for these studies is an oral suspension; however, later in the RFP (first bullet, last sentence) you mention "solid dosage forms". Could you confirm if the DHHS is seeking a solid dosage form for ciprofloxacin and doxycycline?

Answer: DHHS is seeking proposals for studies that will evaluate the home preparation of an oral suspension from solid dosage forms of the antibiotics. Because the targeted populations for these drugs includes children, it is recommended that the proposal include efforts to mask the taste.

3. Phase 2 appears to involve a clinical study (since involves human volunteers). Regarding the nature of the clinical study in phase 2, is it necessary for the clinical study to be conducted in actual volunteers' homes? I ask since such a study design may be larger in scope than a design where volunteers are brought to a simulated home/kitchen.

Answer: The offeror should propose the study design that offers the best study design and the best value to the Government. This approach should support the best quality of data at the lowest price.

4. What is the approximate review date, notification date and start date?

Answer: Evaluation (review) should occur within a month of receipt of proposals. Notification and start date all depend on the extent of questions and discussions with prospective offeror(s).

5. As stated in the RFP, one component of this work is to evaluate "home preparation instructions acceptability of these drugs." Could you clarify, does 'home preparation instructions acceptability' mean that we must obtain the person's attitudes regarding the preparation instructions? For example, Were the instructions easy to follow? Is this something you could do on your own? Were there things you did not understand? Or does this mean something else, like merely observing preparation technique?

Answer: Evaluation of instructions includes the ability of volunteers to comprehend and follow the instructions as well as attitudes such as those mentioned in the question.

6. I have a faculty member who is interested in competing for RFP-BARDA-08-12. In order for me to assist him I need to know what forms your organization requires. I was unable to find this RFP on the Grants.gov site or the Grants.net site. Could you please provide me with some guidance?

Answer: The RFP (request for proposal) is not a grant mechanism. RFP's are used when the binding vehicle will be a contract. There are no standard forms that BARDA requires for RFPs. This program will not involve grants in any form.

7. Regarding RFP-BARDA-08-12, for each doxycycline and ciprofloxacin oral solid dosage forms, there are various doses and manufacturers. Which exact tablet or capsules products should be used as starting materials? Are there particular products that can be assumed to be stock piled? For example, Bayer CIPRO 750mg tablets or generic Barr ciprofloxacin 500mg tablets?

Answer: The offeror should propose starting materials that offers the broadest therapeutic use and best value to the Government.