AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES	
J	1	3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
0001	01-Mar-2010	W23RYX91354002	

6. ISSUED BY CODE W81XWH

USA MED RESEARCH ACQ ACTIVITY
820 CHANDLER ST
FORT DETRICK MD 21702-5014

7. ADMINISTERED BY (If other than item 6) CODE W81XWH

USA MED RESEARCH ACQ ACTIVITY
ATTN: DANA HERNDON
301-619-7140
DANA.HERNDON@US.ARMY.MIL
FORT DETRICK MD 21702

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)

CODE FACILITY CODE

X	9A. AMENDMENT OF SOLICITATION NO. W81XWH-10-R-0029
X	9B. DATED (SEE ITEM 11) 01-Mar-2010
	10A. MOD. OF CONTRACT/ORDER NO.
	10B. DATED (SEE ITEM 13)

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer [X] is extended, [ ] is not extended.

Offer 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 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.

[ ] 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.)

1. Block 9 of the Standard Form 33 is corrected to change the time when solicitation proposals are due:

FROM: 12:00 AM (on 31 March 2010)

TO: 03:00 PM Eastern Daylight Time (on 31 March 2010)

2. Section A - Solicitation/Contract Form, Additional Information, Solicitation Questions is corrected to revise the time when questions are due:

FROM: 3:00 PM, Eastern Standard Time, on Monday, 15 March 2010

TO: 3:00 PM, Eastern Daylight Time, on Monday, 15 March 2010

3. There are no other changes to the solicitation.

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) TEL: EMAIL:	
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 01-Mar-2010

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The following have been modified:
ADDITIONAL INFORMATION

PROJECT TITLE: Development, Preparation, cGMP Manufacture and Testing of Antiplaque Chewing Gum Containing Antimicrobial Peptides for Phase I Clinical Trial

This is a Research and Development requirement.

The solicitation shall result in a Cost-Plus-Fixed-Fee contract.

The period of performance has been estimated. The actual period of performance will be dependent on meeting the requirements of the four milestones described in Section C of this solicitation.

Award shall be made on a Best Value basis.

HISTORICAL INFORMATION:

This solicitation was previously issued as W81XWH-09-T-0397. That solicitation was canceled and is being reissued as Request for Proposal No. W81XWH-10-R-0029.

SOLICITATION QUESTIONS:

Questions concerning this Request for Proposal are due no later than 3:00 p.m., Eastern Daylight Time, on Monday, 15 March 2010. Questions shall be submitted to dana.herndon@us.army.mil by this closing date and time. No questions shall be addressed after this cutoff period. Telephone inquiries will NOT be entertained. Offerors shall submit one set of questions only; multiple emails shall not be accepted. An Amendment to the solicitation will be submitted addressing the answers.

Questions which were asked and answered on Request for Quotations No. W81XWH-09-T-0397 follow:

Question #1: Statement of Work Section 5.1.17.4 (page 7) indicates "KSL-W concentration will not vary within each formulation…" whereas Section 5.1.17.4.1 provides five different formulations with a differing amount of KSL-W for each. On surface, clauses seem contradictory. Please clarify.

Answer: The test gums will contain increasing amounts of peptide and CPC, i.e., five different test doses. The different test doses will begin with a formulation, with each formulation containing an increasing dose of peptide and CPC.

Question #2: Quality Assurance Surveillance Plan (QASP) Section 1.1 (page 13) indicates that the contractor – Fertin Pharma A/S, Denmark – has already been determined. Has Fertin of Denmark already been chosen as the preferred contractor? Has Fertin of Denmark already done some work on this project for the US Army? If so, would we be privy to the information received from Fertin on this project by the US Army?

Answer: This is a full and open competitive solicitation. All offers will be considered in accordance with the evaluation factors provided in FAR Clause 52.212-2 Evaluation—Commercial Items (JAN 1999) of the solicitation.* The QASP has been corrected to remove the names of any potential offerors. Fertin has helped the Army do some preliminary formulation work based on an agreement between Fertin and the Army. At present, the data obtained is not available to the public. However, as allowed within the limits of the agreement with Fertin, the Army intends to use this information in the future development and production of test gum.

*NOTE: The evaluation factors for RFP No. W81XWH-10-R-0029 are found in Section M.

Question # 3: While we have used CPC before in chewing gum, we are unaware of any work regarding peptides. Will the U.S. Army be responsible for filing the appropriate forms with the FDA for the NDA or ANDA this project would seemingly require?

Answer: The Army will be responsible for filing the IND.

Question #4: Could we receive a Safety Data Sheet on the peptide being considered?

Answer: The peptide represents a new entity and there is no MSDS established for the peptide. However, the preclinical animal safety studies have been completed and viewing of the data could be arranged via NDA.

Question # 5: Our plan would include production at our facility, but all testing (including stability testing) [would be] done at 3rd party FDA approved facilities. Would such a proposal be considered responsive to this solicitation?

Answer: It is the preference of the Army that manufacturing of the GMP test gum and formulation and stability testing be conducted at the same GMP facility.

The following information is provided to those interested in responding to this requirement:

At present, we have not established the manufacturing specification for the antiplaque chewing gum; however, we expect to have the test GMP gum manufactured at varying concentrations of the actives as described in the Statement of Work. The chewing gum can be manufactured either by cold-pressed or standard processes. Because of the nature of one of the actives, cold-pressed process may be the process of choice. The actives used in this antiplaque chewing gum include an antimicrobial peptide and a surface active agent and the excipients include sweetener and mild abrasive. The antimicrobial peptide has a broad spectrum of antimicrobial activity against both oral and non-oral bacteria. The peptide is sensitive to high temperatures (60 degrees C) and high humidity (90% RH). For more information, see one of our publications authorized by Faraj et al. AAPS PharmSci Tech. 2007. Article 26.

FREEDOM OF INFORMATION ACT (FOIA) INQUIRIES RELATED TO THE CURRENT CONTRACT SHOULD BE DIRECTED TO:

Mrs. Nancy Gaynor
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAP-A
Fort Detrick, MD 21702-5014

E-mail: nancy.gaynor@us.army.mil
Telephone: 301-619-2389

(End of Summary of Changes)