



RESEARCH DEMONSTRATION COOPERATIVE
AGREEMENTS
Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION

Notice of Grant Award

Issue Date: 09/08/2014



Grant Number: 3U18FD004270-04W1
FAIN: U18FD004270

Principal Investigator:
KEN B MOORE, MA

Project Title: Shellfish Safety Assistance Project

NANCY S. DANIEL
PROGRAM MANAGER
INTERSTATE SHELLFISH SANITATION
209 DAWSON ROAD
COLUMBIA, SC 292231740


Budget Period: 09/01/2014 – 08/31/2015
Project Period: 09/21/2011 – 08/31/2016

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of \$75,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to INTERSTATE SHELLFISH SANITATION CONF in support of the above referenced project. This award is pursuant to the authority of PHS Act, Sec 1706, 42 USC 300u-5, as amended; Sec 2(d), PL 98-551 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

If you have any questions about this award, please contact the Grants Management Specialist and the Project Officer listed in the terms and conditions.

Sincerely yours,

Gladys Melendez-Bohler
Grants Management Officer
Office of Acquisitions & Grants Services
Division of Acquisition Support and Grants
Grants & Assistance Team
FOOD AND DRUG ADMINISTRATION

See additional information below

SECTION I – AWARD DATA – 3U18FD004270-04W1**Award Calculation (U.S. Dollars)**

Federal Direct Costs	\$75,000
Approved Budget	\$75,000
Federal Share	\$75,000
TOTAL FEDERAL AWARD AMOUNT	\$75,000

AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$75,000
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SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (4)	
GRANT NUMBER	TOTAL FEDERAL AWARD AMOUNT
3U18FD004270-04W1	\$75,000
5U18FD004270-04	\$325,000
TOTAL	\$400,000

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
4	\$75,000	\$400,000
5	\$0	\$325,000

* Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:

CFDA Number:	93.103
EIN:	1521656630A1
Document Number:	UFD004270A
Fiscal Year:	2014

IC	CAN	2014
FD	6991782	\$75,000

* Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

FDA Administrative Data:

PCC: CFS3 / OC: 414N / Processed: ERAAPPS 08/28/2014

SECTION II – PAYMENT/HOTLINE INFORMATION – 3U18FD004270-04W1

PHS policy requires that you be informed that the DHHS Inspector General maintains a toll free telephone number (800-368-5779) for receiving information concerning fraud, waste and abuse under the grants and cooperative agreements. Such reports will be kept confidential and callers may decline to give their names if they choose to remain anonymous.

Payments under this award will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Federal Assistance Financing (DFAF), Office of the Deputy Assistant Secretary, Finance, which will forward instructions for obtaining payments. Inquiries regarding the payment should be directed to:

Division of Federal Assistance Financing
DASP/DASF/OS/DHHS
P.O. Box 6021

Grantees are asked to register in the Central Contractor Registration (CCR) database. Information about CCR is available at http://www.grants.gov/applicants/register_ccr.jsp. This registration will be required as electronic grant processing is implemented.

SECTION III – TERMS AND CONDITIONS – 3U18FD004270-04W1

This award is based on the application submitted to, and as approved by, FDA on the above-title project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The PHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. An annual Financial Status Report (SF-269) is required. An original and two copies of this report must be submitted to the FDA Grants Management Officer within 90 days after the expiration date of the budget period.
- f. A Final Program Report, Financial Status Report and Invention Statement must be submitted within 90 days after the expiration date of the project period.
- g. This award notice, including the terms and conditions cited below.

This award has been assigned the Federal Award Identification Number (FAIN) U18FD004270. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Treatment of Program Income: Additional Costs

SECTION IV – FD Special Terms and Condition – 3U18FD004270-04W1

PLEASE NOTE: This award reflects an administrative supplement in the amount of \$75,000. Funds are to be used for the purposes stated below and as provided by e-mail on 8/8/2014 to Nancy Daniel:

Funds to support this Administrative Supplement have been obligated by the Center for Food Safety and Applied Nutrition, Office of Food Safety and shall be used for the purpose of awarding and administering research projects that will advance the science of *Vibrios* and the efficacy of various *Vibrio* control strategies as well as to collect and analyze data and information associated with state and industry *Vibrio* control efforts. The work will further inform existing goals set forth in the current FDA/ISSC *Shellfish Safety Assistance Agreement* (Grant Number U18FD004270).

Reporting Requirements:

1. Periodic program monitoring will be conducted which may be in the form of telephone conversations between the Principal Investigator and the Project Officer/Grants Management Officer/Grants Management Specialist. Program monitoring may also be in the form of site visits.
2. A copy of the annual annual Federal Financial Report (SF425) is required. A copy should be provided electronically, via-email, through your organization signing official/Accountant to the FDA Grants Management contact noted below within 90 days after the end of each budget period. It is important that the grantee establish and maintain internal controls to ensure that all FFRs are current, accurate and provide a complete disclosure of the financial status of the project in accordance with 45 CFR Parts 74.1 and 74.53.

3. Annual Non-competing Continuation Program Progress Reports are two months prior to the end of the current budget year. Forms can be accessed at <http://grants2.nih.gov/GRANTS/FORMS.HTM> These reports must contain the following information:

- a. General progress of the project
- b. Project status in relation to established timelines.

4. The recipient will conduct, when appropriate, an annual Single Audit as required by OMB Circular A-133. This audit must be submitted to the Federal Audit Clearinghouse at the Bureau of the Census within 9 months of the close of their fiscal year. If you need information on your organization's obligations under the Single Audit Act, please visit the following website: <http://harvester.census.gov/sac/> Valuable information is included under the Frequently Asked Questions section of that site.

Delineation of Substantive Involvement:

FDA will:

1. Appoint a Project Officer or Co-Project Officers who will actively monitor the FDA supported program under this award.
2. Retain the right to have prior approval on the appointment of all key personnel substantially supported by the grant.
3. Be directly involved in the guidance and development of the program and the collaborative structure for the program.
4. Participate with the grantee in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings and where appropriate, co-authorship of publications.
5. Have professional scientific and administrative/clerical personnel working in collaboration with the grantee as required.

Failure to comply with the above stated Standard Terms and Conditions could result in the suspension or termination of this grant project.

For Scientific and Programmatic concerns related to this project contact Paul Distefano 301-402-1410

For Administrative and Financial concerns related to this project contact Gladys Melendez Bohler 240-402-7565.

This Grant is Excluded from Expanded Authorities.

Direct inquiries regarding scientific programmatic issues to the official listed below.

Direct inquiries regarding fiscal and/or administrative matters to the grants management specialist listed below.

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise explicitly directed.

STAFF CONTACTS

Grants Management Specialist: Gladys Melendez-bohler

Email: gladys.bohler@fda.hhs.gov **Phone:** 240-402-7565 **Fax:** (301) 827-0505

SPREADSHEET SUMMARY

GRANT NUMBER: 3U18FD004270-04W1

4270

Food & Drug Administration		DATE 5/22/2014	
		1. CENTER/PROGRAM CFSAN	
2. LIST NUMBER FD-004270-03		3. APPROPRIATION NUMBER 75140600	
4. CAN* CAN NO. 6991782 TAG NO. 5184OFS405K1152		5. PMS CODE* 223151/10	
6. OBJECT CLASS 41.41		7. TYPE OF AWARD Non - Competing - Research	
8. GRANT NUMBER 3U18-FD004270-03S/ gms	9. Document # UFD004270A	10: EIN# 1521656630A1	
Ken Moore Interstate Shellfish Sanitation 209 Dawson Road - Suite 2 Columbia, SC 29223-1740			
12. PROJECT PERIOD 09/21/2011-08/31/2016		13. BUDGET PERIOD 09/01/2013-08/31/2014	
14. APPROVED FOR OBLIGATION DIRECT: \$ 75,000 INDIRECT: \$0 \$ FEE: \$0 (SBIR ONLY) TOTAL COST:\$75,000			
15. SPECIAL CONDITIONS <ul style="list-style-type: none"> Please provide Terms and Conditions of Award in addition to those already attached to the award. <p style="text-align: right;">Requisition 1135113 Ref code 370</p>			
16. REMARKS Please scan the signed document to G. Bohler - gladys.bohler@fda.hhs.gov <ul style="list-style-type: none"> 301-827-7175 - Telephone 301-827-0505 - FAX 			
17. PROJECT OFFICER (Print name and Sign; provide telephone #) Phone Number: Paul W. Distefano 240-402-1410 <i>Paul W. Distefano</i>		18. CENTER/OFFICE <i>[Signature]</i> Funds Available: Alexander Hawkins, Budget Director, CFSAN	
19. APPROVED BY DIRECTOR, (or individual with Delegated Authority) Brian Trent, Associate Director for Management, CFSAN			
20. APPROVED BY DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT			
21. CERTIFICATION OF Chief GRANTS MANAGEMENT OFFICER, OAGS and/or Grants Management Officer Gladys Melendez (Bohler) <i>Gmelendez</i>			

