



FOOD AND DRUG ADMINISTRATION

Grant Number: 5U01FD005760-03
FAIN: U01FD005760

Principal Investigator:
Ken B Moore, MBA

Project Title: Shellfish Safety Assistance Project

Ms. Daniel, Nancy S.
Program Manager
209 Dawson Road
Suite 1
Columbia, SC 292231740

Award e-mailed to: ndaniel@issc.org

Budget Period: 09/01/2018 – 08/31/2019
Project Period: 09/01/2016 – 08/31/2021

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of \$500,000 (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 42 USC 241 31 USC 6305 42 CFR 52 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,

Kimberly Pendleton
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 – 5U01FD005760-03

Award Calculation (U.S. Dollars)

Salaries and Wages	\$212,125
Fringe Benefits	\$68,835
Personnel Costs (Subtotal)	\$280,960
Supplies	\$15,750
Travel Costs	\$23,550
Other Costs	\$179,740
Federal Direct Costs	\$500,000
Approved Budget	\$500,000
Federal Share	\$500,000
TOTAL FEDERAL AWARD AMOUNT	\$500,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$500,000

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
3	\$500,000	\$500,000
4	\$500,000	\$500,000
5	\$500,000	\$500,000

* 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: UFD005760A
 PMS AccountType P(Subaccount)
 Fiscal Year: 2018

IC	CAN	2018	2019	2020
FD	6991782	\$440,000	\$500,000	\$500,000
FD	69999AG	\$60,000		

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

FDA Administrative Data:

PCC: CFS3 / OC: 4141 / Processed: FDAKPU 08/03/2018

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01FD005760-03

Grant payments will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Payment Management, Program Support Center (PSC), DHHS, Office of the Deputy Assistant Secretary, Finance. Requests for downloadable forms and inquiries regarding payment should be directed to:

Regular Mailing Address:
 Division of Payment Management
 P.O. Box 6021
 Rockville, MD 20852

Telephone: (301) 443-1060

Included are the following Links & Instructions for drawing down funds, reporting expenditures, required forms, and the help desk info:

Homepage: <http://www.dpm.psc.gov/Default.aspx>

Grant Recipient Information:

http://www.dpm.psc.gov/grant_recipient/grant_recipient.aspx?explorer.event=true

Grant Recipient Forms:

http://www.dpm.psc.gov/grant_recipient/grantee_forms.aspx?explorer.event=true

PMS Help Desk: <http://www.dpm.psc.gov/help/help.aspx?explorer.event=true>

The ONE-DHHS Help Desk for PMS Support is now available Monday – Friday from 7 a.m. to 9 p.m. EST (except Federal Holidays). Phone (877) 614-5533; Email PMSSupport@psc.gov

SECTION III – TERMS AND CONDITIONS – 5U01FD005760-03

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 75.
- d. The HHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. A required Federal Financial Report (FFR) SF-425 must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding
- g. Closeout Requirements (when applicable): A Final Program Progress Activity Report, Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428, and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period.
- h. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

This award has been assigned the Federal Award Identification Number (FAIN) U01FD005760. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Treatment of Program Income:

Additional Costs

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements,

and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

SECTION IV – FD Special Terms and Condition – 5U01FD005760-03

TERMS AND CONDITIONS

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role of activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the FDA as defined below.

A.1. Principal Investigator Rights and Responsibilities

The Principal Investigator will have the primary responsibility for and dominant role in planning, directing, and executing the proposed project, with the FDA staff being substantially involved as a partner with the PI.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and FDA policies.

A.2. FDA Responsibilities

An FDA Program Officer will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The program officer will monitor the grantee periodically. The monitoring may be in the form of telephone conversations, emails, or written correspondence between the project officer/grants management officer and the Principal Investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request, consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the grant, including those that state that future funding will depend on recommendations from the project officer. In addition:

- a. FDA will have prior approval of the appointment of all key administrative and scientific personnel proposed by the grantee.
- b. FDA will be directly involved in the guidance and development of the program. FDA scientists will participate, with the grantee, in determining and carrying out scientific and technical activities. Collaboration will also include data analysis, interpretation of findings and, where appropriate, co-authorship of publications.

Financial Reporting:

A. Cash Transaction Reports

The Federal Financial Report (FFR) has a dedicated section to report Federal cash receipts and disbursements. For recipients this information must be submitted quarterly directly to the Payment Management System (PMS) using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

B. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not be accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

For inquiries regarding the scientific programmatic issues and fiscal and/or administrative matters, please refer to STAFF CONTACTS listed below:

Scientific Program Official: Melissa Abbott
Email: Melissa.Abbott@fda.hhs.gov
Phone: (240) 402-1401

Grants Management Specialist: Kiara Fowler
Email: Kiara.Fowler@fda.hhs.gov
Phone: (240) 402-3099

All formal correspondences/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.

FAILURE TO COMPLY WITH THE ABOVE STATED TERMS AND CONDITIONS COULD RESULT IN THE SUSPENSION OR TERMINATION OF THIS GRANT AWARD.

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: Kiara Fowler
Email: Kiara.Fowler@fda.hhs.gov

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01FD005760-03

INSTITUTION: INTERSTATE SHELLFISH SANITATION CONF

Budget	Year 3	Year 4	Year 5
Salaries and Wages	\$212,125	\$205,955	\$212,125
Fringe Benefits	\$68,835	\$70,165	\$72,270
Personnel Costs (Subtotal)	\$280,960	\$276,120	\$284,395
Supplies	\$15,750	\$17,375	\$18,250
Travel Costs	\$23,550	\$28,930	\$30,375
Other Costs	\$179,740	\$177,575	\$166,980
TOTAL FEDERAL DC	\$500,000	\$500,000	\$500,000
TOTAL FEDERAL F&A	\$0	\$0	\$0
TOTAL COST	\$500,000	\$500,000	\$500,000

Nancy Daniel

From: era-notify@mail.nih.gov
Sent: Friday, August 03, 2018 7:02 PM
To: Nancy Daniel
Subject: NoA: 5 U01 FD005760-03 PI: Moore, Ken
Attachments: FDA_NOA_5U01FD005760-03.PDF

Grant Number: 5 U01 FD005760-03
Principal Investigator: Moore, Ken B
Project Title: Shellfish Safety Assistance Project
Institution: INTERSTATE SHELLFISH SANITATION CONFERENCE
CFDA: 93.103
OC: 4141
PCC: CFS3
Award Issue Date: 08/03/2018
Grants Management Officer: Pendleton, Kimberly

Grants Specialist: FOWLER, KIARA

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