Grant Number: 5U18FD006275-02
FAIN: U18FD006275

Principal Investigator:
Tony Macaluso

Project Title: RFA-FD-17-007: Advancing Conformance with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) (U18)

Mr. Macaluso, Tony
Environmental Health Specialist Supervisor
1001 East Ninth Street
Reno, NV 895200027

Award e-mailed to: genfield@washoecounty.us

Budget Period: 07/01/2018 – 06/30/2019
Project Period: 09/01/2017 – 06/30/2020

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $70,000 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to COUNTY OF WASHOE 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;Sec2(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,

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 – 5U18FD006275-02

Award Calculation (U.S. Dollars)

Travel Costs	$6,152
Consortium/Contractual Cost	$57,484
Federal Direct Costs	$63,636
Federal F&A Costs	$6,364
Approved Budget	$70,000
Federal Share	$70,000
TOTAL FEDERAL AWARD AMOUNT	$70,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$70,000

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$70,000	$70,000
3	$70,000	$70,000

* 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:	1886000138A1
Document Number:	UFD006275A
PMS AccountType	P(Subaccount)
Fiscal Year:	2018

IC	CAN	2018	2019
FD	6990914	$70,000	
FD	6990928		$70,000

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

FDA Administrative Data:
PCC: ORA12 / **OC**: 414P / **Processed**: FDAKPU 06/21/2018

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U18FD006275-02

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) 443-1660

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 – 5U18FD006275-02

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) U18FD006275. 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 (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

SECTION IV – FD Special Terms and Condition – 5U18FD006275-02

SPECIAL PROGRAMMATIC TERMS AND CONDITIONS:

Monitoring Activities

The ORA Project Officer and Technical Advisor will monitor award recipients periodically. The monitoring may be in the form of face-to-face meetings, telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the principal investigator. Periodic site visits with officials of the recipient organization will occur, including program assessments and audits. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be made available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations. Also, the grantee organization shall comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the project will depend on recommendations from the Project Officer and Technical Advisor.

The scope of the recommendation will confirm that:

(1) There has been acceptable progress on the project;
(2) there is continued compliance with all FDA regulatory requirements; and
(3) if necessary, there is an indication that corrective action has taken place.

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the Notice of Award.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf)

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov>; (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000.

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 from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported 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 FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Reporting Requirements

Mid-year progress and End of Year reports are required as part of the grant.
The Mid-year ends December 31st and reporting is required within 30 days.
The End of Year report is due 60 days before the close of the budget period on June 30th. End of year reports are due on May 1st.

Mid-year progress and End of Year reports shall contain the elements below as applicable to their proposal and award, including but not limited to, the following:

1. Detailed progress report on the grantee meeting the project milestones identified in the proposal.

2. Status report on the hiring and training of food program personnel.

3. Certification of current appropriation funding levels for the retail food regulatory program.

4. A strategic plan that accurately reflects when specific objectives and tasks have been, or will be, completed and/or implemented and when new objectives and tasks are identified to advance conformance with the Retail Program Standards. The strategic plan should include significant milestones or action items, anticipated completion dates, responsible personnel, and other required resources.

5. A full description of achievements with conformance to the Retail Program Standards and what activities have been done to promote more effective control of foodborne illness risk factors.

6. A completed Program Self-Assessment and Verification Audit Form for each standard or an equivalent form or process documenting the current status of the jurisdictions. The Self-Assessment and Verification Audit Form can be found in the Voluntary National Retail Food Program Standards.

The final program progress report shall provide full written documentation of the entire project and summaries of accomplishments and goals, as described in the grant application. The documentation shall be in a form and contain sufficient detail such that other agencies could reproduce the final project. The final program progress report should also detail the strategy to continue advancing conformance with the Retail Program Standards (current and future versions).

This award is subject to the Special Requirements of the RFA-FD-17-007entitled, "Advancing Conformance with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS)" is hereby incorporated by reference as special terms and conditions of this award. Copies of this announcement may be obtained from the Grants Management Contact referenced in the award.

This award is subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable to you based on your recipient type and the purpose of this award. This includes any requirements in Parts I and II (available at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm) of the HHS GPS that apply to an award.

Although consistent with the HHS GPS, any applicable statutory or regulatory requirements, including 45 CFR Part 75, directly apply to this award apart from any coverage in the HHS GPS that apply to an award.

Salary Cap: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Current salary cap level is $179,700.

STANDARD TERMS AND CONDITIONS:

2.A. Cooperative Agreement Terms and Conditions of Award

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 (HHS) 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, FDA's 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 in the 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 FDA as defined below.

2.A.1. Principal Investigator Rights and Responsibilities

The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, or programmatic aspects of the cooperative agreement and for day-to-day management of the project or program. The PD(s)/PI(s) will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have sufficient clearance and/or background checks to work on this project or program. This individual will work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements.

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.

Additionally PD/PIs will:

1. Participate in site visits or attend meetings as requested by the FDA. A portion of the budget should be reserved for such travel.

2. FDA may also request data be made available through speaking engagements and publications, presentations at scientific symposia and seminars, while making sure that confidentiality and privacy of the data is protected.

3. The awardees will provide FDA any data obtained from investigations if requested by FDA.

4. Any publication or oral presentation of regarding outcomes of this grant must undergo FDA Office of Research and Center review and approval process. This process can take 30-90 days.

2. A.2. FDA Responsibilities

An FDA Project Officer (PO) will have substantial programmatic involvement as described below. The PO is the official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO’s responsibilities include, but are not limited to, post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the Grants Management Officer (GMO). The PO and the GMO work as a team in many of these activities.

Additionally, an agency program official will be responsible for the scientific and programmatic stewardship of the award and will be named in the award notice.

FDA will provide technical monitoring and/or direction of the work, including monitoring of data analysis, interpretation of analytical findings and their significance.

FDA will assist and approve (as deemed appropriate) the substance of publications, co-authorship of publications and data release.

Funding Restrictions:

These awards may only be used for achieving and sustaining conformance with the Retail Program Standards within retail food regulatory programs. The FDA will provide up to three years of funding, contingent on continued availability of federal funds. Budgets are limited to $70,000 (direct and indirect costs) of funding requested and must reflect the actual needs of the proposed activities. Allowable costs include:

1) Audio/visual materials such as videotapes, DVDs, public service announcements, etc.

2) Consultant services

3) Employee salaries, wages and fringe benefits

4) Rental, purchasing, calibration, and maintenance of supplies and equipment, including investigational, GPS interface, communication, and laboratory

5) Indirect costs

6) Recruitment costs for hiring new employees

7) Registration fees

8) Purchase or development of IT equipment, software, and support

9) Shipping and mailing of equipment and supplies

10) Travel

11) Speaker fees

12) Conducting standardizations

13) Training programs, including the development, delivery, and attendance

14) Subcontracting to third parties (other than local/county/tribal agencies) is allowed but limited to 25% of each year's award. No limit exists for subcontracting to local/county/tribal agencies.

Non-allowable costs:

1) Facilities, work, and training reimbursed under other cooperative agreements, grants, contracts, and other funding mechanisms shall remain distinct and separate from this cooperative agreement.

2) Vehicle purchases are not permitted.

3) Cooperative agreement funds may not be utilized for new building construction; however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 10% of the grant award amount.

4) Cooperative agreement funds may not be utilized for uniforms or clothing.

Additional funding restrictions may be part of the Notice of Award.

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 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.

Performance Progress Reporting:

1. Annual progress reports are required. The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR).

2. Grants with Multiple Years: When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR).

Information regarding submitting the RPPR is available at
https://era.nih.gov/erahelp/commons/default.htm#cshid=1020

PROGRAM INCOME:

1. The grantee is required to report any Program Income generated during the Project Period of this grant. Except for royalty income generated from patents and inventions, the amount and disposition of Program Income must be identified on lines 10 (l), (m), (n), and (o) of the grantee's Federal Financial Report (FFR) SF-425.

2. Examples of Program Income include (but are not limited to): fees for services performed during the grant or sub-grant period, proceeds from sale of tangible personal or real property, usage or rental fees, patent or copyright royalties, and proceeds from the sale of products and technology developed under the grant.

3. Any Program Income generated during the Project Period of this grant by the grantee or sub-grantee is subject to the Addition Alternative for Program Income and, therefore, must only be used to further the goals of the project for which this grant was awarded.

PRIOR APPROVAL:

All requests that require prior approval must include the award number and bear the signature of an authorized official of the grantee business office as well as that of the PI/PD. Any requests involving funding issues must include a new proposed budget and a narrative justification of the requested changes. If a grantee questions whether prior approval is required for an activity or cost, they should contact the assigned Grants Management Specialist prior to expenditure of funds for clarification. Below are activities that require prior approval from FDA:

1. CHANGE IN SCOPE OR OBJECTIVES
2. CHANGE IN KEY PERSONNEL

3. CHANGE IN GRANTEE ORGANIZATION
4. DEVIATION FROM TERMS AND CONDITIONS OF THE AWARD
5. CARRYOVER OF UNOBLIGATED BALANCES
6. NO COST EXTENSIONS
7. SIGNIFICANT REBUDGETING

ACKNOWLEDGEMENT OF FEDERAL SUPPORT:

When issuing statements, press releases, publications and other documents describing projects or programs funded in whole or in part with Federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state:

*Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant **U18FD006275.** Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.*

FDA/ORA CONTACT INFORMATION:

Grants Management Contact:
Gordana Zuber
Grants Management Specialist
Food and Drug Administration, MSC HFA-500
5630 Fishers Lane, Rockville, MD 20857
Phone: 301-348-1747
Email: gordana.zuber@fda.hhs.gov

Programmatic Contact:
Maribeth G. Niesen
Project Officer
Office of Regulatory Affairs (ORA), Office of Partnerships
Food and Drug Administration
Phone: 513-679-2704
Email: maribeth.niesen@fda.hhs.gov

Technical Advisor:
Your Regional Retail Food Specialist
Office of Regulatory Affairs
Food and Drug Administration

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

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 directed.

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: Gordana Zuber
Email: gordana.zuber@fda.hhs.gov **Phone**: 301-348-1747

Program Official: Maribeth Niesen
Email: Maribeth.Niesen@fda.hhs.gov

SPREADSHEET SUMMARY
GRANT NUMBER: 5U18FD006275-02

INSTITUTION: COUNTY OF WASHOE

Budget	Year 2	Year 3
Travel Costs	$6,152	$13,960
Other Costs		$20,304
Consortium/Contractual Cost	$57,484	$29,372
TOTAL FEDERAL DC	$63,636	$63,636
TOTAL FEDERAL F&A	$6,364	$6,364
TOTAL COST	$70,000	$70,000