



FOOD AND DRUG ADMINISTRATION

Grant Number: 1U18FD006224-01 REVISED
FAIN: U18FD006224

Principal Investigator:
Eric Hueste

Project Title: To achieve and maintain full conformance with the Manufactured Food Regulatory Program Standards (MFRPS).

Mr. Fischer, Bret
Director, Division of Administration
920 Wildwood Drive
P.O. Box 570
Jefferson City, MO 651020570

Award e-mailed to: grants@health.mo.gov

Budget Period: 08/05/2017 – 07/31/2019
Project Period: 08/05/2017 – 07/31/2019

Dear Business Official:

The Food and Drug Administration hereby revises this award (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to MISSOURI STATE DEPT/ HEALTH & SENIOR SRV 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,

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 – 1U18FD006224-01 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	\$160,211
Fringe Benefits	\$77,284
Personnel Costs (Subtotal)	\$237,495
Supplies	\$1,327
Travel Costs	\$50,099
Other Costs	\$8,358

Federal Direct Costs	\$297,279
Federal F&A Costs	\$50,824
Approved Budget	\$348,103
Federal Share	\$348,103
TOTAL FEDERAL AWARD AMOUNT	\$348,103

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$0

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$348,103	\$348,103

* 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: XXXXXXXXXX
 Document Number: UFD006224A
 PMS AccountType P(Subaccount)
 Fiscal Year: 2017

IC	CAN	2017
FD	6990928	\$348,103

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

FDA Administrative Data:

PCC: ORA1 / **OC:** 4141 / **Processed:** FDAKPU 08/07/2018

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U18FD006224-01 REVISED

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 – 1U18FD006224-01 REVISED

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) U18FD006224. 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 – 1U18FD006224-01 REVISED

08/06/2018: This award is being revised to provide approval of the grantee's no-cost extension 07/31/2019 as approved by grants management and the Program Official with no additional cost to the Government as requested in accordance with the correspondence of date 08/03/2018.

SPECIAL PROGRAMMATIC TERMS AND CONDITIONS:

The grantee must maintain a food safety inspection contract in satisfactory standing with the FDA throughout the cooperative agreement.

Provide funding certification of the current year's budget for the State manufactured food regulatory program to demonstrate that these funds have supplemented, and not replaced, State allocations. If a decrease in State allocations does occur during the cooperative agreement, a detailed justification must be provided to FDA for approval.

Key personnel (minimum of 2) must attend an annual face-to-face meeting (as determined by FDA OP) as a condition of the award. The face-to-face meeting will be held in the continental US for a minimum of 2.5 days. The grantee should budget accordingly to cover all travel expenses using cooperative agreement funds.

Facilities, work, training, and other expenses reimbursed under the FDA food safety inspection contract and other funding mechanisms must remain distinct and separate from the cooperative agreement. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, equipment, supplies, and other costs, under the food safety inspection contracts and other funding mechanisms and the cooperative agreement.

The grantee must fully participate in initiatives supporting the MFRPS, such as an annual face-to-face meeting (as determined by FDA OP), committees, OP MFRPS conference calls, sharing of best practices and resources, on-site visits, and FDA assessment to determine implementation and conformance. During on-site visits and program assessments, all key personnel, records (electronic and paper-based), facilities, and other resources necessary for FDA to conduct a complete program assessment will be made available.

If the grantee is located in a state which, at the time of application submission, has a laboratory awarded a current FDA ISO Laboratory Accreditation Cooperative Agreement, the regulatory program grantee will provide for the collection of samples (FDA regulated products only) to support laboratory capacity development and product surveillance. The applicant must also demonstrate the ability to perform any enforcement or other follow-up activities based on sample results. Sampling plans will be developed collaboratively with the laboratory to support the objectives of both programs.

All appendices as found in the most current version of the MFRPS or alternate forms that are equivalent, databases/IT systems, records, and other documents will be made available upon request to FDA for purposes of monitoring program progress towards meeting the goals of the cooperative agreement and achieving conformance with the MFRPS.

Future funding will be dependent on recommendations from the Project Officer and the availability of funds. The Project Officer will base the recommendation on whether acceptable progress has been made in achieving significant to full conformance with the MFRPS within the required timeframes, approval of an ESS (when applicable), implementation of SEP(s) (if pursued), continued compliance with all FDA regulatory requirements, and, if applicable, whether a corrective action plan has been developed and corrective actions are being satisfactorily

implemented. The grantee must implement corrective action plans for all observations reported by the FDA Office of Operations, Audit Staff during scheduled MFRPS program assessment validation audits (PAVAs) and full program audits.

A determination of the grantee's conformance with the MFRPS will be made based upon multiple factors, including the grantee's assessment, progress reports, on-site visits, and audits. If progress concerns are identified, then the grantee will be placed in special condition status and be required to implement corrective actions. Failure to implement corrective actions may result in reduction of funding or termination of the cooperative agreement.

TERMS AND CONDITIONS:

This award is subject to the Special Requirements of the **RFA-FD-17-005** entitled, **"Conformance with the Manufactured Food Regulatory Program Standards (MFRPS) (U18)"** 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 MFRPS, development and implementation of Standard Enhancement Projects (SEPs), and other projects that support the intended outcomes of the cooperative agreement program. Funds should be requested in the budget for key project personnel to travel to meetings, on-site visits, and audits with FDA program staff to discuss the project. A portion of budgeted travel funds should also be set aside for key personnel to attend an annual face-to-face meeting (as determined by FDA OP) and committee meetings supporting the MFRPS. Training needs should also be anticipated and budgeted for accordingly. Prior approval from FDA for budget modifications of > 10% of the total award or substantial changes to the project proposal is required.

Allowable costs include:

- 1) Audiovisual 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
- 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 (including per diem for meals)
- 11) Speaker fees
- 12) Subcontracting to third parties (other than local/county/tribal agencies conducting work on behalf of the State manufactured food regulatory agency) is allowed but limited to 25% of each year's award.

Non-allowable costs:

- 1) Facilities, work, and training reimbursed under other funding mechanisms must remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under the food safety inspection contracts and other funding mechanisms and these cooperative agreements.
- 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) Food is not an allowable cost.
- 5) Please also refer to the HHS Grants Policy Statement for additional information regarding costs.

Pre-Award Costs:

According to PHS policy, if pre-award costs are necessary, they may be approved by the authorized institutional official(s).

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.

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#csid=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 **U18FD006224**. 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:
Kiara Fowler
Grants Management Specialist
Food and Drug Administration, MSC HFA-500
5630 Fishers Lane, Rockville, MD 20857
Phone: 240-402-3099
Email: Kiara.Fowler@fda.hhs.gov

Programmatic Contact:
Brett Weed
Project Officer
Phone: 404-253-2268
Email: Brett.Weed@fda.hhs.gov

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

Program Official: Brett Weed
Email: Brett.Weed@fda.hhs.gov

SPREADSHEET SUMMARY

GRANT NUMBER: 1U18FD006224-01 REVISED

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 1
Salaries and Wages	\$160,211
Fringe Benefits	\$77,284
Personnel Costs (Subtotal)	\$237,495
Supplies	\$1,327
Travel Costs	\$50,099
Other Costs	\$8,358
TOTAL FEDERAL DC	\$297,279
TOTAL FEDERAL F&A	\$50,824
TOTAL COST	\$348,103