Grant Number: 3U18FD006422-03S1
FAIN: U18FD006422

Principal Investigator:
Eric Hueste, BS

Project Title: FSMA Human Foods Preventive Controls Implementation Expansion

Ms. Mahaney, Marcia
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: 09/01/2020 – 06/30/2021
Project Period: 09/01/2018 – 06/30/2021

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $150,000 (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;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

FOOD AND DRUG ADMINISTRATION

Additional information follows

SECTION I – AWARD DATA – 3U18FD006422-03S1

Award Calculation (U.S. Dollars)

Salaries and Wages	$64,346
Fringe Benefits	$40,216
Personnel Costs (Subtotal)	$104,562
Supplies	$1,864
Travel Costs	$18,115
Other Costs	$4,442
Federal Direct Costs	$128,983
Federal F&A Costs	$21,017
Approved Budget	$150,000
Federal Share	$150,000
TOTAL FEDERAL AWARD AMOUNT	$150,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$150,000

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3)	
GRANT NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3U18FD006422-03S1	$150,000
5U18FD006422-03	$460,000
TOTAL	**$610,000**

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$150,000	$610,000
4	$0	$460,000
5	$0	$460,000

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

Fiscal Information:

CFDA Number:	93.367
EIN:	[redacted]
Document Number:	UFD006422A
PMS AccountType	P(Subaccount)
Fiscal Year:	2020

IC	CAN	2020
FD	6990914	$150,000

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

FDA Administrative Data:
PCC: ORA20 / **OC**: 4141 / **Processed**: FDAKPU 08/31/2020

SECTION II – PAYMENT/HOTLINE INFORMATION – 3U18FD006422-03S1

Grant payments will be made available through the DHHS Payment Management System (PMS). Please go to https://pms.psc.gov/ to find more information on user access, payment, reporting and FAQs.

Inquiries should be directed to:

ONE-DHHS—the PMS Help Desk, providing assistance to all system users. Support is available Monday - Friday from 7 a.m. to 9 p.m. ET (except Federal Holidays): 1-877-614-5533 or email PMSSupport@psc.gov.

The HHS Inspector General (IG) maintains a toll-free telephone number, 1-800-447-8477, for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Such reports are kept confidential, and callers may decline to give their names if they choose to remain anonymous.

SECTION III – TERMS AND CONDITIONS – 3U18FD006422-03S1

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. The Funding Opportunity Announcement in which this award is issued under.
g. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

This award has been assigned the Federal Award Identification Number (FAIN) U18FD006422. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Expanded Authorities:
Unless otherwise stated in Section IV – Special Terms and Conditions, this award is not under expanded authorities.

Reporting Requirements:
All FDA grants require both Financial and Performance reporting.

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. All annual FFRs must 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 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.

Performance Progress Reporting:

When multiple years (more than one budget period) are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually as required in the Notice of Award. Annual RPPRs must be submitted using the RPPR module in eRA Commons. The annual RPPR must include a detailed budget. Annual RPPRs are due no later than 60 days prior to the start of the next budget period.

Failure to submit timely reports may affect future funding. Additional Financial and Performance Progress reports may be required for this award. Any additional reporting requirements will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Salary Caps:
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 Executive Level II of the Federal Executive Pay Scale.

Certificates of Confidentiality – 42 U.S.C. 241(d)
Awardees are responsible for complying with all requirements to protect the confidentiality of identifiable, sensitive information that is collected or used in biomedical, behavioral, clinical, or other research (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs) funded wholly or in part by the Federal Government. See 42 U.S.C. 241(d). All research funded by FDA, in whole or in part, that is within the scope of these requirements is deemed to be issued a "Certificate of Confidentiality" through these Terms and Conditions. Certificates issued in this manner will not be issued as a separate document.

Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, understand they are also subject to the requirements of 42 U.S.C. 241(d). Awardees are also responsible for ensuring that any subrecipient that receives funds to carry out part of the FDA award involving a copy of identifiable, sensitive information protected by these requirements understand they are also subject to subsection 42 U.S.C. 241(d).

Acknowledgment of Federal Support:
When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter "statements")--describing the projects or programs funded in whole or in part with FDA federal funds, the recipient must clearly state:

1. the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
2. the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by FDA financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following statements.

If the FDA Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

> This [project/publication/program/website, etc.] [is/was] supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as

part of a financial assistance award [FAIN] totaling $XX with 100 percent funded by FDA]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

If the FDA Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

> This [project/publication/program/website, etc.] [is/was] supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling $XX with XX percentage funded by FDA/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement. Any amendments by the recipient to the acknowledgement statement must be coordinated with FDA. If the recipient plans to issue a press release concerning the outcome of activities supported by FDA financial assistance, it should notify FDA in advance to allow for coordination.

Additional prior approval requirements pertaining to Acknowledgement of Federal Support, publications, press statements, etc. may be required, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Prior Approval:
All prior approval requests must be submitted using the Prior Approval module in eRA Commons. Any requests involving budgetary issues must include a new proposed budget and a narrative justification of the requested changes. If there are any questions regarding the need or requirement for prior approval for any activity or cost, the grantee is to contact the assigned Grants Management Specialist prior to expenditure of funds. The following activities require prior approval from FDA:

1. Carryover of Unobligated Balances
2. No Cost Extensions
3. Change in Grantee Organization
4. Significant Rebudgeting
5. Change in Scope or Objectives
6. Deviation from Terms and Conditions of Award
7. Change in Key Personnel which includes replacement of the PD/PI or other key personnel as specified on the NoA.
8. Disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved PD/PI. No individual may be committed to more than 100% professional time and effort. In the event that an individual's commitment exceeds 100%, the grantee must make adjustments to reduce effort. For FDA-sponsored projects, significant reductions in effort (i.e., in excess of 25% of the originally proposed level of effort) for the PD/PI and key personnel named on named on this Notice of Award must receive written prior approval from FDA.

Additional prior approval requirements may be required for this award, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Audits and Monitoring:

Audit Requirements:

1. Recipients of Federal funds are subject to annual audit requirements as specified in 45 CFR 75.501 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=8040c4036b962cc9d75c3638dedce240&ty=HTML&h=L&r

=PART&n=pt45.1.75#se45.1.75_1501). Grantees should refer to this regulation for the current annual Federal fund expenditure threshold level which requires audit.
2. Foreign recipients are subject to the same audit requirements as for-profit organizations (specified in 45 CFR 75.501(h) through 75.501(k).
3. For-profit and foreign entities can email their audit reports to AuditResolution@hhs.gov or mail them to the following address:

   U.S. Department of Health and Human Services
   Audit Resolution Division, Room 549D
   Attention: Robin Aldridge, Director
   200 Independence Avenue, SW
   Washington, DC 20201

Monitoring:

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with Federal, DHHS and FDA requirements. However, to fulfill their role in regard to the stewardship of Federal funds, FDA monitors our grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to FDA.

1. **Desk review:** FDA grants monitoring specialists will periodically reach out to recipients to request information for the completion of desk reviews. Requested information may include:
   - Policies and procedures
   - List of grant expenditures
   - Accounting records
   - Supporting documents (e.g., invoices, receipts, paystubs, timesheets, contracts, etc.)
   - Financial statements
   - Audit reports
   - Other related documentation
2. **Site visits:** FDA will conduct site visits when necessary and will notify the recipient with reasonable advance notice of any such visit(s).
3. **Foreign entities:** All Foreign entities are subject to the same monitoring requirements as domestic entities. Foreign entities covered under immunity Executive Orders will provide supporting documents for monitoring requirements unless such an action is a violation of the Executive Orders. Recipients may discuss with the FDA to come up with an alternate approach to satisfy the award monitoring requirements.

All recipients will make reasonable efforts to resolve issues found, including audit findings. Successful resolutions to issues are important as they are part of the grant performance review. All recipients are responsible for submitting all requested information in an expeditious manner. **Failure to submit timely reports and/or respond to inquiries from FDA may affect future funding or enforcement actions, including withholding, or conversion to a reimbursement payment method.**

Financial Conflict of Interest (FCOI):
This award is subject to the Financial Conflict of Interest (FCOI) regulation at 42 CFR Part 50 Subpart F.

Closeout Requirements (when applicable):
A Final Research Performance Progress Report (FRPPR), Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428 (if applicable), and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period. All closeout documents must be submitted electronically in eRA Commons.

The Final FFR must indicate the exact balance of unobligated funds and may not reflect unliquidated obligations. There must be no discrepancies between the Final FFR expenditure data and FFR cash transaction data in the Payment Management System (PMS). It is the recipient's responsibility to reconcile reports submitted to PMS and to the FDA.

Program Income:
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.

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.

Any Program Income generated during the Project Period of this grant by the grantee or sub-grantee will be treated as identified below.

Treatment of Program Income:
Additional Costs

Other:
This award is subject to the requirements of 2 CFR Part 25 for institutions to maintain an active registration in the System of Award Management (SAM). Should a consortium/subaward be issued under this award, a requirement for active registration in SAM must be included.

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 – 3U18FD006422-03S1

8/28/2020 - This supplement is awarded to provide additional funding to support staff time and travel for inspections and training as described in the approved revised budget.

Restrictions:
All grantees are expected to perform a minimum of the respective percentage (based on the MFRPS funding tier referenced in the next bullet) full-scope PCHF inspections that should be performed based upon the firm inventory and risk-based inspection frequency during the Federal Fiscal Year 2020 - 2021.? For grantees already meeting the minimum of percentage required for the number of full-scope PCHF inspections should remain constant or increase.? FDA can provide to each grantee the annualized needs to each state, which outlines an average number of inspections that are required to perform by FDA to meet FSMA inspection frequencies and; performs the respective percentage of full-scope PC inspection based on their MFRPS Tier:

- Tier 3 ($300,000/yr award under the MFRPS track of RFA-FD-18-001) - 10%
- Tier 2 ($225,000/yr award under the MFRPS track of RFA-FD-18-001) - 15%
- Tier 1 ($150,000/yr award under the MFRPS track of RFA-FD-18-001) - 25%

Program funds may not be used for any purpose other than those directly tied to the goals of the cooperative agreement.
Non-allowable costs:
Facilities and work reimbursed under the FDA human food safety inspection contract and other funding mechanisms must remain distinct and separate from the cooperative agreement.
Vehicle purchases are not permitted.
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.
Clothing and uniforms, with the exception of personal protective equipment (PPE).
Other items listed in the HHS Grants Policy Statement

Additional Reporting Requirements:

All FDA grants require annual financial and performance progress as stated in Section III. This award has additional financial and performance reporting requirements as outlined below.

Financial

Mid-year interim financial reports are required for this award. The interim financial report should be submitted via email to the listed Grants Management Specialist and Program Official by [January 30, 2021]. The Federal Financial Report (SF-425) which can be downloaded at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm should be used to submit interim financial reports via email to the Grants Management Specialist and Program Official.

Performance

Mid-year interim performance progress reports are required for this award. The interim performance progress reports should be submitted via email to the listed Grants Management Specialist and Program Official by [January 30, 2021].
The interim performance progress report should include:
1. Detailed progress report on the grantee meeting the project goals detailed in the cooperative agreement and identified in the application;
2. Status report on the hiring and training of personnel if undertaken as a part of the PCHF funding option;
3.?? Status on the installation and operational readiness of any equipment, including IT, or software purchased; and
4.? Any programmatic issues or concerns.
Reporting for this supplement will be appended to the annual or mid-year reporting for the parent award issued under RFA-FD-18-001.
Annual progress reports must contain the elements below as applicable to their application and award, but are not limited to, the following:
1. Description of program improvements and demonstration of measurable implementation achieved by the funding provided under this expansion supplement;
2.? An estimate (in total dollars) of in-kind contributions toward accomplishing the goals of the cooperative agreement during the reporting period; and
3. Report on progress to implement an audit program, including Phase II and III food safety inspection contract audits as described in FDA Field Management Directive 76 (FMD-76), if the program was not already operating in Phase II or III at the start date;
*NOTE:? Additional Reporting templates may be developed and made available for grantees to use after awards are made, to assist with reporting of progress achieved and/or data elements from the project goals (or outputs) listed in this FOA, and to improve monitoring for the progress and objectives of this Cooperative Agreement.
The final program progress report must provide full written documentation of the project and summaries of accomplishments and goals, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other state, local, and tribal governments could reproduce the final project. The final program progress report should also detail the strategy, including commitment of personnel, resources, and funding.

Cooperative Agreement 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 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 the FDA as defined below.
The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, or programmatic aspects of the grant and for day-to-day management of the project or program. The PD/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 has 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.
The PD(s)/PI(s) will have the primary responsibility for:

a. Developing and implementing systems necessary for communications among the various study organizational components.? All data and samples to be shared freely by methods and within time periods to be specified by the Program Official.
b. Agreeing to work cooperatively with FDA, and
c. Overall management of the project,

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 DHHS, PHS, and FDA policies.
FDA staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
Substantive involvement by the awarding agency is inherent in the cooperative agreement award.? Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement.
The Grants Project Team may consist of a Grants Management Specialist, Program Official, Project Manager, and Technical Advisor(s).? The Grants Project team collaborates to review the progress of the grantee, and will have substantial involvement in the design, implementation, and evaluation of program activities, and dissemination of program results and outcomes, above and beyond routine grant monitoring.?
The Grants Project Team may utilize the grantee's progress reports, site visits, audit reports, FDA human food safety contract data, and other supporting documentation to determine if the terms and conditions of the award are met and satisfactory progress is being made.? Each team member works in consultation with each other, as needed, throughout the duration of the project.? A description of each team member involved with the program are described below.
An FDA Grants Management Specialist (GMS) will be assigned and named in the Notice of Award.? The GMS oversees the administrative, financial, business and other non-programmatic aspects of the program.? These activities include, but are not limited to the following:?

-
  - Maintains the official grantee file.

- Monitors administrative and financial aspects of grantee activities, and
- Monitors and manages applications and required reports on eRA Commons,
- Provides guidance on administrative, business, fiscal aspects of grants management to grantees and FDA program staff,

An FDA Program Official (PO) will be assigned and named in the Notice of Award.? The PO is accountable for the programmatic oversight of the grant to include coordination, with the Project Manager, on the technical aspects of the grant.? S/he ensures the budget of grantees are reasonable and costs are allowable and allocable.? The PO reviews the progress reports to verify the budget proposed includes only allowable expenses that support the project goals and objectives.?? The PO also assists with post-award monitoring and establishing a corrective action plan, if necessary.
An FDA Project Manager (PM) will be assigned to the program. The FDA PM is the responsible official for the programmatic, scientific, and/or technical aspects of assigned applications and cooperative agreements. The FDA PM will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below.
The PM will have substantial involvement in the design, implementation, and evaluation of program activities, and dissemination of program results and outcomes, above and beyond routine grant monitoring. Substantial involvement by FDA/ORA includes, but is not limited to, the following:

-
  - Assist in coordinating multi-program pilot projects.
  - Monitor project/program performance, including review of progress reports and conducting visits; and
  - Provision of programmatic technical assistance;
  - Development Develop programs to meet the FDA mission;
  - Participate in data analysis, interpretation of findings, and where appropriate, co-authorship of publications;
  - Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
  - Conduct technical sessions with the grantee, as deemed necessary by FDA;
  - Evaluate the supported program, including development of program-level performance measures, consistent data collection, and reporting procedures and protocols;
  - Actively monitor the supported program via telephone conversations, webinars, e-mails, written correspondence, or periodic site visits;

- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Provide guidance, direction, and technical assistance in project planning, implementation, and evaluation;

An FDA Technical Advisor(s) will be assigned to each enrolled program. The Advisor will primarily provide subject matter expertise for program activities and will work cooperatively with the PO and PM to help monitor and report grantee status/progress including sharing of information and historical backgrounds. The FDA Technical Advisor will have programmatic involvement as described below including, but not limited, to the following:

-
  -
    - Advise on technical aspects of program activities.
    - Assist with development of programs to meet the FDA mission; and
    - Assist with trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing; and
    - Assist in the sharing of information developed by the grantee and collaboration to achieve implementation of the project goals. Examples may include SOPs, MOUs, training programs, and record keeping systems;
    - Conduct technical sessions with the grantee, as deemed necessary by FDA;
    - Review grantee reports and provide technical comment on progress,
    - Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
    - Provide guidance and technical assistance in project planning, implementation, and evaluation;

Unless another governance structure is mutually agreed upon, the Project Manager shall serve as the primary point of contact for the dissemination of FDA policy and project planning for milestones/objectives.
Additionally, an agency program official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Monitoring Activities

The Program Official and Project Manager/Technical Advisor(s) 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 Program Official/Grants Management Officer/Technical Advisor(s) and the principal investigator. In addition, periodic site visits with officials of the recipient organization may also occur to assess progress. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be 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 Program Official and Project Manager/Technical Advisor(s).

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 adequate corrective actions have taken place to address any identified problems.
Areas of Joint Responsibility include:

- [None; all responsibilities are divided between awardees and FDA staff as described above.]

Other:
Funding provided under this expansion supplement may be used to fund PCHF Rule-related activities which were previously allocated to the budget under another funding option of the RFA-18-001 award. For reallocations exceeding 10% of the total award, approval is required from the Grants Management Team.
The purpose of this cooperative agreement is to advance efforts for nationwide implementation of the PCHF Rule. The cooperative agreements will provide funding for additional personnel, equipment, supplies, and training to support activities related to achieving adoption, implementation, and maintenance of the PCHF Rule.
The grantee must maintain a food safety inspection contract with the FDA throughout the cooperative agreement. Continued funding for this cooperative agreement funding option are subject to the execution and completion of contract work according to the requirements of the contract.
Recipients must have an executed non-public information sharing agreement under 21 CFR Part 20.88 no later than the start date of the grant award.
The grantee must agree to participate in mentoring partnerships to develop, advance, share, and implement best practices for regulatory activities.

Program Manager:? Jocelyn Ramos, Tel: 510-337-6894, email: jocelyn.ramos@fda.hhs.gov

?

Direct inquiries regarding scientific, technical and programmatic issues to the program official listed below.

Direct inquiries regarding fiscal, grants policy, procedures 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: Daniel Lukash
Email: daniel.lukash@fda.hhs.gov **Phone**: 240-402-7596

Program Official: Laurie Keppley
Email: Laurie.Keppley@fda.hhs.gov

SPREADSHEET SUMMARY
GRANT NUMBER: 3U18FD006422-03S1

INSTITUTION: MISSOURI STATE DEPT/ HEALTH & SENIOR SRV

Budget	Year 3	Year 4	Year 5
Salaries and Wages	**$64,346**		
Fringe Benefits	**$40,216**		
Personnel Costs (Subtotal)	**$104,562**		
Supplies	**$1,864**		

Travel Costs	**$18,115**		
Other Costs	**$4,442**		
TOTAL FEDERAL DC	**$128,983**		
TOTAL FEDERAL F&A	**$21,017**		
TOTAL COST	**$150,000**	**$0**	**$0**