Recipient Information

1. Recipient Name
HEALTH AND SENIOR SERVICES, MISSOURI DEPARTMENT OF
920 WILDWOOD DR

JEFFERSON CITY, 65109

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
[redacted]

4. Employer Identification Number (EIN)
[redacted]

5. Data Universal Numbering System (DUNS)
878092600

6. Recipient's Unique Entity Identifier
UETLXV8NG8F4

7. Project Director or Principal Investigator
Mark Jenkerson, BS

8. Authorized Official
Marcia Mahaney
grants@health.mo.gov
5737516014

Federal Agency Information

9. Awarding Agency Contact Information
Gordana Zuber

FOOD AND DRUG ADMINISTRATION
gordana.zuber@fda.hhs.gov
301-348-1747

10. Program Official Contact Information
Aaron Dagres

FOOD AND DRUG ADMINISTRATION
Aaron.Dagres@fda.hhs.gov

Federal Award Information

11. Award Number
5U18FD006422-05

12. Unique Federal Award Identification Number (FAIN)
U18FD006422

13. Statutory Authority
PHS Act,Sec 1706,42 USC 300u-5,as amended;Sec2(d),PL 98-551

14. Federal Award Project Title
MFRPS-to achieve & maintain full conformance, RRT-Improve food safety in Missouri, FPTF-To organize Food Protection Task Force meetings.

15. Assistance Listing Number
93.367

16. Assistance Listing Program Title
Flexible Funding Model - Infrastructure Development and Maintenance for State Manufactured Food Regulatory Programs

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/01/2022 – **End Date** 06/30/2023	
20. Total Amount of Federal Funds Obligated by this Action	$460,000
20 a. Direct Cost Amount	$393,380
20 b. Indirect Cost Amount	$66,620
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$460,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$460,000
26. Project Period Start Date 09/01/2018 – **End Date** 06/30/2023	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,226,941

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Lisa Ko

30. Remarks

PLEASE REVIEW ALL TERMS AND CONDITIONS IN SECTIONS III AND IV. "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

SECTION I – AWARD DATA – 5U18FD006422-05

Award Calculation (U.S. Dollars)	
Salaries and Wages	$214,305
Fringe Benefits	$136,320
Personnel Costs (Subtotal)	$350,625
Materials & Supplies	$5,689
Travel	$11,867
Other	$17,199
Subawards/Consortium/Contractual Costs	$8,000
Federal Direct Costs	$393,380
Federal F&A Costs	$66,620
Approved Budget	$460,000
Federal Share	$460,000
TOTAL FEDERAL AWARD AMOUNT	$460,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$460,000

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$460,000	$460,000

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

Fiscal Information:

Document Number:	UFD006422A
PMS AccountType:	P(Subaccount)
Fiscal Year:	2022

IC	CAN	2022
FD	6990914	$460,000

* 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**: Ko, Lisa 07/01/2022

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U18FD006422-05

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.

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 – 5U18FD006422-05

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.

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:
This award is not covered under Expanded Authorities. Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval. All no cost extension requests require prior approval. Please see section Prior

Approval on Prior Approval requirements.

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.

If the budget period end date falls within:	**then annual FFR is due by:**
January, February, March	June 30th
April, May, June	September 30th
July, August, September	December 31st
October, November, December	March 31st

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.

For grant awards not covered under Expanded Authorities, Carryover and No Cost Extension (NCE) requests will require prior approval. All Carryover and NCE requests should be submitted using the Prior Approval module in eRA Commons. ****Please review the section on Expanded Authorities to determine if this award is covered/not

covered under Expanded Authorities and whether prior approval is needed for carryover and no cost extension requests.****

The following activities require prior approval from FDA on all awards:

1. Change in Grantee Organization
2. Significant Rebudgeting
3. Change in Scope or Objectives
4. Deviation from Terms and Conditions of Award
5. Change in Key Personnel which includes replacement of the PD/PI or other key personnel as specified on the NoA.
6. 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 (FFFR) SF-425, Final Invention Statement (FIS) HHS-568 (if applicable), Tangible Personal Property Report SF-428 (if applicable), and Statement of Disposition of Equipment (if applicable) must be submitted within 120 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). The expended funds reported on the Final FFR must exactly match the disbursements reported on the grantee's report to the Payment Management System and the charge advances in 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

Prohibition on certain telecommunications and video surveillance services or equipment:
(a) As described in CFR 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

(1) Procure or obtain,
(2) Extend or renew a contract to procure or obtain; or
(3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or

any subsidiary or affiliate of such entities).

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

ii. Telecommunications or video surveillance services provided by such entities or using such equipment.

iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

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 – 5U18FD006422-05

ADDITIONAL PRIOR APPROVAL REQUIREMENTS:

In addition to the standard Prior Approval requirements in Section III, this award has additional Prior Approval requirements as outlined below.

- Prior approval is required for significant rebudgeting of 10% or more of the total funds authorized under the current year's award.

Additional Terms and Conditions for MFRPS Funding track (as applicable)

State manufactured food regulatory programs are expected to designate a MFRPS Project Coordinator with overall responsibility for implementation of the strategic improvement

plan as required by the Manufactured Food Regulatory Program Standards. Key personnel (minimum of two) must attend an annual face-to-face meeting (as determined by FDA OP) as a condition of the award. Unless explicitly instructed to attend another meeting, the annual Manufactured Food Program Standards Alliance (MFRPA) meeting serves as the required face-to-face meeting.

State manufactured food regulatory programs in the MFRPS Development funding track are expected to achieve conformance with the MFRPS before Year 5 of the cooperative agreement.

State manufactured food regulatory programs in the MFRPS Maintenance funding track are expected to maintain conformance with the MFRPS throughout the duration of the award.

If the grantee is in a state that receives funding under an active FDA cooperative agreement for maintaining and/or expanding ISO 17025 accreditation for analysis of human food, the regulatory program grantee must provide for the collection of product samples 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 in cooperation with the laboratory to support the objectives of both programs.

Samples must consist solely of FDA-regulated food commodities in interstate commerce. Retail-prepared foods, shellfish, Grade A dairy, and products subject to regulation by the US Department of Agriculture (amenable meats, poultry, processed egg and catfish) may not be used to satisfy this requirement.

Additional Terms and Conditions for RRT funding track (as applicable)

Awardees receiving funding under the RRT track must have in place a valid non-public information sharing agreement with FDA per 21 CFR 20.88

A minimum of two (2) key RRT personnel must attend an annual face-to -face RRT meeting (as determined by FDA OP) and at least one person representing the RRT must attend the biennial Integrated Foodborne Outbreak Response Management (InFORM) Conference and the Regional PulseNet/OutbreakNet meetings (held in non-InFORM years) as a condition of the award.

Additional Terms and Conditions for FPTF funding track (as applicable)

All conference material (promotional materials, agenda, publications and internet sites) related to this project must include an acknowledgement of FDA grant support and a disclaimer stating the following: “Funding for this conference was made possible [in part] by [insert grant number] from [insert FDA name]. The views expressed in written conference 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 mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”

Additional Terms and Conditions for Special Project funding track (as applicable)

FDA reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes any copyrighted works that are outcomes from these funding tracks, including curriculum, course content, objectives, learning outcomes,

presentations, manuals, scripts, exercises, handouts, reports, documents or other tangible materials produced by the awardee. FDA may authorize others to reproduce, publish, or otherwise use such works for Federal purposes.

Additional Terms and Conditions for Preventive Controls (PC) Implementation Expansion Supplement track (as applicable)

All grantees are expected to perform a minimum of the respective scope PCHF inspections that should be performed based upon the firm inventory and risk-based inspection frequency during the Federal Fiscal Year 2022-2023.

The FDA will conduct a verification assessment of the states program's implementation of the program standards if the state receives financial assistance to implement these standards. All observations and findings from the verification assessment must be addressed within the state's strategic improvement plan. The grantee must cooperative and available if a verification assessment is requested.

This supplement track award provides funding to support information sharing development and/or implementation and coordination of IT data exchange capabilities, such as NFSDX and ORAPP. If NSFDX and ORAPP functionalities are already implemented by your state, you may use funds for training auditors and new staff to perform full scope Preventive Controls (PC) inspections.

Non-allowable costs:

a. 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.

b. Vehicle purchases are not permitted.

c. 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.

d. Clothing and uniforms, with the exception of personal protective equipment (PPE). Other items listed in the HHS Grants Policy Statement Financial.

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 January30, 2023. 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, Program Official, and Program Managers by January 30, 2023.

Reporting

Mid-year and final progress reports must contain the elements below:

- Detailed progress report on the grantee meeting the project milestones detailed in the cooperative agreement, proposal, strategic plan, conditions of the award, etc. Goals and objectives should be outlined in detail and specific progress reported.
- Status report on the hiring and training of cooperative agreement funded personnel and other manufactured food program personnel.
- Status report on the purchasing, development, and operational readiness of any equipment, computers, or software purchased.
- Identify any pending issues or concerns that may affect accomplishing the objectives and goals of the cooperative agreement.
- A corrective action plan must be submitted if the objectives and goals of the cooperative agreement are not being met. The corrective action plan must detail the tasks, responsible personnel, and updated timeframes to ensure satisfactory performance and meet the deliverables required under the grant.

Optional program specific reporting elements:

- Certification of current State appropriation funding levels for the State Manufactured Food Regulatory Program.
- Identify the number of Full Time Employees (FTEs) or FTE Equivalents are currently employed to conduct manufactured food inspections and related operations.
- Current data for the state programs manufactured food firm inventory, number of field staff trained by inspection type, inspections completed, and samples collected in the previous fiscal year and inspections and samples planned for the current year.
- A list of Servicing Laboratories with applicable services and roles.
- Confirm the inspection types for which the state program has regulatory authority.
- Describe the current status and relevant efforts and activities conducted within the reporting period for the following:

    1. MFRPS appendices.
    2. Standards Improvement Plan.
    3. Annual performance review of field inspections, inspection reports, and sample reports as well as compliance and enforcement actions if applicable and as defined by the program.
    4. MFRPS Outcome 1: State manufactured food regulatory programs will achieve implementation and maintain conformance with the MFRPS,

which is recognized as a critical element to creating a national, fully integrated food safety system.

5. MFRPS Outcome 2: Provide the FDA the foundation for pursuing regulatory action based upon the findings of State manufactured food regulatory programs. Grantees will provide the FDA the foundation to improve quality of contracts, coordination of inspections, investigations and enforcement to effectively and efficiently protect public health.
6. MFRPS Outcome 3: Develop strategies for achieving implementation and maintaining conformance with the MFRPS that can be replicated or leveraged across state programs to promote national consistency.
7. MFRPS Outcome 4: If applicable, provide sample collection for the state laboratory to maintain ISO 17025 accreditation, to support capacity development and product surveillance. In addition, sampling plans will be developed in cooperation with the laboratory to support MFRPS objectives.
8. MFRPS Outcome 5: Ensure continuing education training and documentation for applicable staff under manufacturing foods.
9. MFRPS Objective 1: Provide an approved exit strategy of sustainability for the MFRPS by the fifth year of funding under a MFRPS cooperative agreement to address sustainability of program accomplishments including commitment of personnel, resources and funding to sustain full conformance with the MFRPS.
10. State Programmatic Goals as applicable and defined by the program.

Additional optional programmatic requirements for the mid-year report

Report on the personnel funded by this award, including project role and calendar months funded. Submission of the following documents in the most current version of the MFRPS reviewed and updated within the current budget period (see below list). These documents may be found in the 2019 version of the MFRPS available at https://www.fda.gov/media/131392/download

a. Appendix 1.1 and 1.2 or alternate form that is equivalent

b. Appendices 2.1and 2.2 or alternate form that is equivalent

c. Appendix 3.1 or alternate form that is equivalent

e. Appendices 4.1, 4.2, 4.3 and4.4 or alternate forms that are equivalent

f. Appendix 5.1 or alternate form that is equivalent g.Appendices 6.1 and 6.2 or alternate form that is equivalent h.Appendix 7.1 or alternate form that is equivalent

i. Appendices 8.1 and 8.2 or alternate form that are equivalent

j. Appendix 9.1 or alternate form that is equivalent k.Appendix 10.1 or alternate form that is equivalent

l. Submission of a strategic improvement plan, as defined in the current version of the MFRPS, updated within the current budget period to demonstrate program

advancement in achieving conformance with the MFRPS.

Additional requirements for the final progress report:

The final End of Project RPPR report at the conclusion of the award must include an Exit Strategy of Sustainment (ESS), describing the recipient's plan for continued maintenance of the regulatory infrastructure developed under this award.

Special consideration for programs in RRT Maintenance & Development

All progress reports (mid-year and final) must contain, but are not limited to the following:

- Progress & achievements for each yearly goal.
- Progress & achievements for other projects identified by the grantee in the application or after receiving funding.
- Summary of significant RRT responses or other activities within the timeframe for the report, including status of AAR & lessons learned/recommendations for improvement
- Point of Contact and Project Key Personnel
- Pending Issues/Concerns and Proposed Solutions

Special consideration for programs in FPT

Food Protection Task Forces must meet at least once annually with a formal agenda and/or evaluation of meeting.

The mid-year progress report submitted for the overall cooperative agreement (MFRPS Development or Maintenance Tracks) does not need to include a mid-year progress report for the FPTF funding option. The FPTF funding option must be included in the final progress reports. FPTF progress reports must address the following:

- The FPTF official name, mission and annual goals and objectives
- A description of their FPTF structure, leadership and membership
- The number of meetings, trainings, and workshops supported and provide a description or provide copies of agendas and supporting materials (handouts, slides, etc.)
- Copies of FPTF PPT, job aids, and other tools and resources developed by FPTF to meet their goals and objectives for sharing with other task forces and stakeholders
- Describe and list the number of attendees represented per meeting, training or workshop (e.g., federal, state, local, tribal and territorial human and animal food (HAF) protection, public health, agriculture and regulatory agencies, retail, industry, academia, and consumers) or provide a copy of the meeting, training, workshop etc. sign-in sheet that captures the names, emails, and affiliations of the attendees
- Describe what went well (success stories and lessons learned)

- Describe how the FPTF promoted the integration of an efficient statewide human and animal food protection system that maximized the protection of public health.
- Describe the FPTF efforts to foster communication, education and outreach
- Describe what could be done better
- Describe what could be done to improve the outreach activity event
- Discussions and decisions resulting from these activities (reports, recommendations, questions etc.), including the replicability across other state task forces
- Identification of an integration activity to address each year (see FOA Part 2, Section I, Sub-section 3 (FPTF), objective 3, above) and provide an update on the activity in the annual report.
- Identification of any issues encountered during the implementation and/or adoption of FSMA or other rules/codes/ordinances.
- Describe any resources and tools developed by the FPTF to meet their goals and objectives for sharing with other task forces and stakeholders

Special consideration for programs in Special Projects

Mid-year and final progress reports for the Special Projects funding option should describe progress made to date. MFRPS special project tasks should be included in the strategic plan (in respective standard area) to identify objectives each quarter/year and progress made.

The Final Progress Report must include an evaluation/final report, including: lessons learned, results, analysis of effectiveness and impact, full written documentation of the project and summaries of accomplishments and goals. 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 most recent assessment by FDA should verify the program is maintaining conformance with the MFRPS.

Special consideration for programs in PC Implementation Expansion Supplement

Optional program specific reporting elements:

Describe the current status and relevant efforts and activities conducted within the reporting period for the following:

- PC Expansion Outcome 1: IT infrastructure such as additional resources, support or IT-data exchange development/implementation (i.e. National Food Safety Data Exchange (NFSDX) and the Office of Regulatory Affairs Data Exchange (ORAPP), and information sharing coordination).
- PC Expansion Outcome 2: If NSFDX and ORAPP functionalities are already implemented by your state, funds can be used for training auditors and new staff to perform full scope Preventive Controls (PC) inspections.

The mid-year progress report should include your progress made since the receipt of the award. The program must limit the objectives to IT data exchange capabilities, such as NFSDX and ORAPP, and information sharing coordination.

The interim performance progress report should include:

- Detailed progress report on the grantee meeting the project goals detailed in the cooperative agreement and identified in the application;
- Status report on the hiring and training of personnel if undertaken as a part of the PCHF funding option;
- Status on the installation and operational readiness of any equipment, including IT, or software purchased; and
- Any programmatic issues or concerns.

Final progress reports must contain the elements below as applicable to their application and award, but are not limited to including a description of program improvements and demonstration of measurable implementation achieved by the funding provided under this expansion supplement.

Special consideration for programs Compliance and Enforcement Expansion Supplement

Mid-year progress reports shall contain the elements below as applicable to the grantee proposal and award, but are not limited to, the following:

- Detailed progress report on the grantee meeting the project goals detailed in the cooperative agreement and identified in the application;
- A comprehensive list of violative samples referred by the collaborating food testing laboratory
- A summary of investigative actions undertaken in response to violative sample referrals from the food testing laboratory, including a summary of findings, and all compliance and enforcement activities conducted (advisory, administrative, and/or judicial).
- Any programmatic issues or concerns

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.

Program funds may not be used for any purpose other than those directly tied to the goals of the cooperative agreement.

Program Manager:

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

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