**Recipient Information**

**1. Recipient Name**
MISSOURI DEPARTMENT OF HEALTH & SENIOR SERVICES
920 WILDWOOD DR
JEFFERSON CITY, MO 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

Mark.Jenkerson@health.mo.gov
5737519523

**8. Authorized Official**
Barbara Gills
Barbara.Gills@health.mo.gov
1-573-522-8356

**Federal Agency Information**

**9. Awarding Agency Contact Information**
Melissa Giorgi
Program Support Specialist
FOOD AND DRUG ADMINISTRATION
melissa.giorgi@fda.hhs.gov

**10. Program Official Contact Information**
Jocelyn Ramos

FOOD AND DRUG ADMINISTRATION
Jocelyn.Ramos@fda.hhs.gov

**Federal Award Information**

**11. Award Number**
5U2FFD008115-02

**12. Unique Federal Award Identification Number (FAIN)**
U2FFD008115

**13. Statutory Authority**
FSMA, Section 210 FSMA, Section 210

**14. Federal Award Project Title**
Missouri Department of Health and Senior Services Flexible Funding Model

**15. Assistance Listing Number**
93.103

**16. Assistance Listing Program Title**
Food and Drug Administration Research

**17. Award Action Type**
Non-Competing Continuation

**18. Is the Award R&D?**
Yes

| Summary Federal Award Financial Information | |
|---|---|
| **19. Budget Period Start Date** 07/01/2024 – **End Date** 06/30/2025 | |
| **20. Total Amount of Federal Funds Obligated by this Action** | $267,006 |
| 20 a. Direct Cost Amount | $247,095 |
| 20 b. Indirect Cost Amount | $42,905 |
| **21.** Authorized Carryover | $0 |
| **22.** Offset | $22,994 |
| **23.** Total Amount of Federal Funds Obligated this budget period | $267,006 |
| **24. Total Approved Cost Sharing or Matching, where applicable** | $0 |
| **25. Total Federal and Non-Federal Approved this Budget Period** | $290,000 |
| **26. Project Period Start Date** 09/15/2023 – **End Date** 06/30/2026 | |
| **27.** Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period | $557,006 |

**28. Authorized Treatment of Program Income**
Additional Costs

**29. Grants Management Officer - Signature**
Stephanie Bogan

**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 – 5U2FFD008115-02**

**Award Calculation (U.S. Dollars)**

| | |
|---|---|
| **Salaries and Wages** | $125,860 |
| **Fringe Benefits** | $80,412 |
| **Personnel Costs (Subtotal)** | $206,272 |
| **Materials & Supplies** | $9,384 |
| **Travel** | $14,123 |
| **Other** | $8,516 |
| **Subawards/Consortium/Contractual Costs** | $8,800 |
| | |
| **Federal Direct Costs** | $247,095 |
| **Federal F&A Costs** | $42,905 |
| **Approved Budget** | $290,000 |
| **Federal Share** | $267,006 |
| **Less Unobligated Balance** | $22,994 |
| **TOTAL FEDERAL AWARD AMOUNT** | $267,006 |
| | |
| **AMOUNT OF THIS ACTION (FEDERAL SHARE)** | $267,006 |

| SUMMARY TOTALS FOR ALL YEARS | | |
|---|---|---|
| **YR** | **THIS AWARD** | **CUMULATIVE TOTALS** |
| 2 | $267,006 | $267,006 |
| 3 | $290,000 | $290,000 |

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

**Fiscal Information:**

| | |
|---|---|
| **Document Number:** | UFD008115A |
| **PMS AccountType:** | P(Subaccount) |
| **Fiscal Year:** | 2024 |

| IC | CAN | 2024 | 2025 |
|---|---|---|---|
| FD | 6990914 | $267,006 | $290,000 |

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

**FDA Administrative Data:**
**PCC**: ORA01 / **OC**: 4141 / **Processed**: 08/08/2024

**SECTION II – PAYMENT/HOTLINE INFORMATION – 5U2FFD008115-02**

Acceptance of this award including the "Terms and Conditions" is acknowledged by the recipient 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 – 5U2FFD008115-02**

Acceptance of this award including the "Terms and Conditions" is acknowledged by the recipient when funds are drawn down or otherwise obtained from the grant payment system.

Failure to adhere and comply with the terms and conditions of award, may result in disallowances, enforcement actions such suspension, termination, withholding of support and/or conversion to a reimbursement payment method.

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. 2 CFR Part 200 and 45 CFR Part 75, currently in effect or implemented during the period of the award.
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) U2FFD008115. 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. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. All annual FFRs must be submitted electronically using the Payment Management System (PMS). 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 a grant is under expanded authorities, the recipient must indicate the carryover amount in Section 12. Remarks of the annual FFR.

| **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, recipients 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)**
Recipients 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.

Recipients 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). Recipients 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 recipient 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 Recipient 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 recipient 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). Recipients 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 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 Federal Financial Report (FFFR) SF-425 must be submitted in the Payment Management System (PMS) within 120 days after the expiration date of the project period. Recipients have 90 days after the project period end date to liquidate all obligations in PMS. All obligations must be liquidated prior to the submission of the Final FFR. 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 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 recipient 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 recipient'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 recipient or sub-recipient 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.

You must administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on

complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

- You must take reasonable steps to ensure that your project provides meaningful access to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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**SECTION IV – FD Special Terms and Condition – 5U2FFD008115-02**

**Please note: This grant will be partially funded based on the grantee's unobligated balance of $22,994 from year 01, which will be used as an authorized offset for fiscal year 2024. $267,006 of new FY2024 funds will be awarded for this grant. The total approved budget including the offset for grant 5U2FFD008115-02 - 02 will be $290,000 In the event that the estimated unobligated balance from year 01 is less than the estimated amount provided by the grantee, no additional Federal Funds will be made available to offset a deficit.**

Participants in this program must fully comply with all corrective action plans implemented or in progress during the project period covered by this NOA.
Federal Financial Reports (FFR) must be submitted each year on January 30th (mid-year FFR) and September 30th (end of year FFR).

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 meeting, in person or virtually if no in-person meeting is offered (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 annual meeting.

State manufactured food regulatory programs in the MFRPS Development funding track are expected to achieve conformance with the MFRPS before year 6 of funding for MFRPS implementation under this or any other combination of cooperative agreements funding the MFRPS program. If the state program is not currently deemed to be in

conformance (as documented in the most recent assessment by FDA/ORA/OHAFO/Audit Staff), the program must address any unmet program elements or documentation requirements in their strategic improvement plan.
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 a state program does not remain in full conformance, corrective actions must be enacted in coordination with the FDA technical advisors.

If recipients are a part of the Laboratory Flexible Funding Model (LFFM), they will apply their MFRPS response, enforcement, and regulatory framework to conduct follow-up inspections, investigations (including traceback/forward), and enforcement actions (including embargos, recalls, warning letters, and closures) to positive and violative samples identified as part of the LFFM cooperative agreement. Coordination with the Rapid Response Team (RRT) and activation, if applicable, is required for recipients also participating in that award (RFA-FD-23-019).
(a) Recipients will commit to coordinating response and compliance follow-up on LFFM samples with the FDA in real-time, to include sharing findings and compliance actions or other follow-up activities discussing regulatory/compliance strategy with the FDA.
(b) If a potentially violative LFFM sample comes to a MFRPS program but is outside of the MFRPS program's regulatory authority/jurisdiction, the MFRPS program agrees to identify and notify the appropriate state/federal agencies with jurisdiction, and to notify the FDA.
(c) Potentially violative LFFM samples may come to the MFRPS program from any laboratory participating in the LFFM Human Food Product Testing track for microbiology or chemistry. This includes – samples collected by LFFM laboratories within the same state as the MFRPS program (may or may not be the primary servicing laboratory for MFRPS); samples collected by other states/analyzed by other LFFM laboratories where the potentially violative product is traced back to the MFRPS program's state.
(d) Recipients will collect samples at the manufacturer, and other locations, in accordance with the collection instructions for each hazard-commodity pair on the approved LFFM sample plan, as needed.
(e) Recipients will build the necessary regulatory and compliance response infrastructure to investigate and respond to violative samples, including qualified personnel, IT resources, and regulatory authorities.

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."

Task Forces funded under this grant must establish and maintain organizational governance documentation (mission statement, vision statement, charter) and have a clearly defined resource-development and educational focus, quantifiable outputs, and measurable public health impact/outcomes.

Submit copies of FPTF presentations, job aids, educational resources, and other materials developed in part by this funding to the Office of Partnerships annually.

Performance
Mid-year progress reports are required for the 2024-2025 budget period. The mid-year progress reports should be submitted via email to the listed Grants Management Specialist, Program Official and Program Managers.
An annual progress report and final progress report are required for this award describing the status of completing each milestone/objective described above.
In addition to the above-named reports, all grantees are required to submit a Research Performance Progress Report (RPPR) in eRA Commons by May 1, 2025.

Program Specific Reporting:
In accordance with 5 CFR 1320.5(b), the approved OMB CONTROL NUMBERS: 0910-0909 and 0910-0601 will be displayed on all forms provided to grantees to report information and data for this cooperative agreement program, including the FFM Program Report Form (mid-year, annual, and final reporting) and MFRPS Appendices. Grantees are strongly encouraged to use the reporting forms provided to ensure that all progress reporting requirements are met, however, grantees may submit the equivalent in another written, electronic format.
The data elements that will be requested include, but are not limited to the following:

Reporting
Mid-Year report elements
a. Develop a current and working strategic improvement plan (SIP) to address program gaps and/or corrective actions.
b. Detailed progress report on the grantee meeting the project milestones detailed in the cooperative agreement, proposal, conditions of the award, etc.

Goals and objectives should be outlined in detail and specific progress reported.
c. Status report on the hiring and training of cooperative agreement funded personnel and other manufactured food program personnel.
d. Status report on the purchasing, development, and operational readiness of any equipment, computers, or software purchased.
e. Identify any pending issues or concerns that may affect accomplishing the objectives and goals of the cooperative agreement.
â€¯
Annual report elements:
Develop a current and working strategic improvement plan (SIP) to address program gaps and/or corrective actions.
Required Appendices (or alternate form that is equivalent). 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 2022 version of the MFRPS available at https://www.fda.gov/media/131392/download:
Appendix 1.1
Appendix 1.2
Appendix 2.1
Appendix 2.2
Appendix 3.1
Appendices 4.1
Appendix 4.3a
Appendix 4.4a
Appendix 4.5a
Appendix 5.1
Appendices 6.1
Appendix 6.2 â€¯
Appendix 7.1
Appendix 8.1
Appendix 9.1
Appendix 10.1
The numbers of hours spent updating the SIP and appendices.
Documentation of the calculation of the required number of inspectors to inspect manufactured food firms in the state program’s inventory at a frequency that is based on the manufactured food firm’s risk classification and the necessary inspection and travel time. Also include the number of Full Time Employees (FTEs) or FTE Equivalents are currently employed to conduct manufactured food inspections and related operations.
Detailed progress report on the grantee meeting the project milestones detailed in the cooperative agreement, proposal, 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.
Report on the personnel funded by this award, including project role and calendar months funded.

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.
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. â€¯
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:
â€¯
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.
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.
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.
MFRPS Outcome 4: If applicable, provide sample collection for the state laboratory to maintain ISO 17025:2017 (or current version) accreditation, to support capacity development and product surveillance. In addition, sampling plans will be developed in cooperation with the laboratory to support MFRPS objectives.
MFRPS Outcome 5: Ensure continuing education training and documentation for applicable staff under manufacturing foods.
MFRPS Objective 1: Provide an approved exit strategy of sustainability for the MFRPS by Year 3 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.
State Programmatic Goals as applicable and defined by the program.
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Special consideration for programs in FPTF:
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 annual progress reports and final progress reports. FPTF progress reports must address the following:
1) Convene at least one task force meeting each year with the explicit purpose of informing, educating, and soliciting input from external

stakeholders on items relevant to executing an effective Integrated Food Safety System at all levels within the respective state.
2) Convene at least one governance meeting with diverse membership to update the vision & mission statement, organizational governance documentation, and the logic model depicting the focus and measurable impact of the Food Protection Task Force.
3) Annually report quantified metrics and measurements demonstrating the various integration and task force activities conducted by the task force directly and as an indirect result of the task force to demonstrate overall impact of this funding track.
4) Submit copies of FPTF presentations, job aids, educational resources and other materials developed in part by this funding to the Office of Partnerships annually. special project tasks should be included in the strategic improvement plan to identify objectives and progress made.

Special consideration for programs in Dietary Supplement Track:
The Dietary Supplement funding option must be included in the mid-year, annual progress reports and final progress reports. Progress reports must describe the current status, relevant efforts and activities conducted within the reporting period including:
• Detailed progress report on the grantee meeting the project goals detailed in the cooperative agreement and identified in the application to include:

1. Training

The program training plan must be updated to include dietary supplement coursework and field training for inspectors engaging in these types of inspections. The state program training plan for dietary supplements should satisfy the training elements in the MFRPS. The training plan will provide a foundation for evidence collection and development, and data acceptability for dietary supplement inspections. An evaluation of the program training plan using data from inspections, samples, and regulatory actions should be performed to determine if the training program needs to be updated to support advisory/regulatory action under your own authorities or by FDA, when necessary.
The program shall identify and document any improvements (such as updates, modifications, or additions) to the program training plan that are needed to promote evidence collection and support possible regulatory actions. The training required for conducting environmental and product sampling to support dietary supplement inspections should also be incorporated into the training program, as appropriate.
Must identify and designate sufficient staff (minimum of 1) to serve as qualified field inspection trainers to provide dietary supplement training for staff as necessary to perform dietary supplement inspections. Training required for the designated person(s) must be identified and completed. Recipients will conduct the in-field training

necessary to ensure staff are qualified to independently conduct dietary supplement inspections and any required sampling (environmental and product).

a. Auditing

As part of the state contract, the state program is expected to move towards implementation of an audit program to support the dietary supplement inspection program. Once implemented, the audit program should include auditing of dietary supplement inspections. As available, the recipient should collect audit data on dietary supplement inspections, inspection reports, and sample collections and reports to evaluate general inspector and program data to identify any gaps and corrective actions needed.

3. Compliance implementation strategies

Recipients will establish inspection and compliance programs which incorporates the requirements of 21 CFR Part 111. Programs will analyze their existing regulatory authority and identify strategies to address any gaps in existing laws and regulations. Programs will analyze their existing enforcement capabilities for dietary supplements and identify gaps in existing procedures. Recipients will work towards development of enforcement strategies appropriate for a dietary supplement inspection program including identifying critical observations, methods for monitoring chronic violators and chronic violations in conformance with Standard 6 of the MFRPS.

4.â€¯â€¯â€¯â€¯â€¯ Program improvement and infrastructure development
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Recipients will identify and provide the framework to address the gaps in agency infrastructure necessary to fully adopt and implement the cGMPs for Dietary Supplements Rule as a part of the manufactured food regulatory program. Infrastructure needs may include personnel, IT, regulatory foundation, training, updating procedures and records, management programs, and laboratory. Recipients should consider information sharing capabilities with FDA in this assessment, as appropriate. Recipients should also propose how project developed capabilities will be maintained after the conclusion of the project.

5.â€¯â€¯â€¯â€¯â€¯ Other outreach activities
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Develop an outreach plan (as required in Standard 7) and associated materials related to dietary supplement regulation and compliance as part of the state program's overall outreach plan. Recipients should consider outreach to industry, including presentations at conferences,

Food Protection Task Force meetings, website updates and/or other outreach efforts as appropriate.

6.â€¯â€¯â€¯â€¯â€¯ Joint work planning and enforcement
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FDA and state personnel will meet as necessary to develop and monitor progress in work planning for dietary supplement facilities under inspection by both agencies to ensure mutually beneficial results. When discussing work planning, best practices, such as those published by the Partnership for Food Protection (PFP), may be used as a resource to guide these meetings. The recipient should evaluate current enforcement tools, strategies, and trends to determine their effectiveness and share findings with FDA. Recipients are also encouraged to assist with updating guidance documents and participate in pilot projects to advance joint work planning, information sharing, firm reconciliation and enforcement actions between the state and FDA, as necessary.

7.â€¯â€¯â€¯â€¯â€¯â€¯â€¯Any programmatic issues or concerns; and
8.â€¯â€¯â€¯â€¯â€¯â€¯â€¯A description of program improvements and demonstration of measurable implementation achieved by the funding provided under this track.
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Non-allowable costs:
a. Facilities and work reimbursed under other FDA 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.

Direct inquiries regarding fiscal, grants policy, procedures and/or administrative matters to the grants management specialist listed on page one of the Notice of Award (NoA).

Direct inquiries regarding scientific, technical and programmatic issues to the program official listed on page one of the Notice of Award (NoA).

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.