STATEMENT OF WORK
Pathways for Regulatory Innovation and Strategic Modernization (PRISM)

Contracting Agency:	U.S. Food and Drug Administration (FDA)
Contractor:	Reagan-Udall Foundation for the FDA (RUF)
Contract Type:	Sole Source Contract
Statutory Authority:	21 U.S.C. § 379dd; Section 770 of the FD&C Act
Period of Performance:	September 30, 2026 – September 29, 2027
Place of Performance:	Washington, D.C. / Virtual / As Specified by Requirement
Contracting Officer (CO):	TBD

SECTION 1 — BACKGROUND

The U.S. Food and Drug Administration (FDA) is the federal agency responsible for protecting and promoting the public health of all Americans through the regulation and supervision of food safety, human and veterinary drugs, biological products, medical devices, cosmetics, and tobacco products. Fulfilling this mission requires continuous, evidence-based engagement across a broad spectrum of scientific, clinical, and public health disciplines — from the development of novel medical devices and rare disease diagnostics, to the safety of cosmetics and the quality of generic drugs, to the modernization of food inspection systems and the advancement of nicotine use disorder treatment. Across all of these areas, FDA must convene diverse stakeholders, synthesize complex evidence, and translate scientific input into sound regulatory policy — activities that benefit from an independent, trusted partner operating at arm's length from the agency.

The Reagan-Udall Foundation for the FDA (RUF) was established by Congress precisely to serve that role. Created under Title VI of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85, enacted September 27, 2007, and codified at 21 U.S.C. § 379dd, RUF is an independent, private, non-profit corporation with a statutory mandate to advance FDA's mission by modernizing medical, veterinary, food, food ingredient, and cosmetic product development; accelerating innovation; and enhancing product safety. By law, RUF's Board of Directors may not include Federal employees, and RUF is expressly prohibited from participating in FDA regulatory decision-making or providing advice on specific regulatory policy matters. This independence is not incidental — it is the foundation of RUF's value as a convener. Stakeholders across industry, academia, patient advocacy organizations, healthcare providers, state and local government, and the public are more likely to engage candidly, share concerns openly, and accept outputs as credible when dialogue occurs in a neutral, non-governmental forum.

Federal law expressly authorizes FDA to award grants, contracts, memoranda of understanding (MOUs), and cooperative agreements to RUF in support of the agency's mission (21 U.S.C. § 379dd). The Pathways for Regulatory Innovation and Strategic Modernization (PRISM) framework has served as the primary vehicle for FDA-RUF collaboration, enabling a diverse portfolio of stakeholder engagements, independent evaluations, scientific convenings, and operational assessments across FDA's Centers and Offices. Through PRISM, RUF has demonstrated the capacity to recruit and coordinate expert panels; facilitate public workshops, private roundtables, and listening sessions; conduct landscape reviews and stakeholder

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interviews; produce white papers and summary reports; and engage more than 170 stakeholders on individual food safety initiatives alone.

The eleven (11) project requirements described in this Statement of Work (SOW) span FDA's Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Office of Chief Scientist (OCS), Office of Cosmetics and Colors (OCAC), and Human Foods Program (HFP). They address some of the most pressing regulatory science and public health challenges facing the agency today: advancing safety standards for emerging neurotechnologies; reducing the diagnostic odyssey for rare disease patients; improving the quality and transparency of real-world evidence for medical devices; countering scientifically unsupported narratives about generic drug quality; developing FDA's cosmetovigilance capacity under MoCRA; modernizing the federal-state food inspection system; and improving treatment access for nicotine use disorder. Individually, each requirement addresses a distinct public health priority. Collectively, they reflect FDA's commitment to science-based, transparent, and stakeholder-informed regulatory modernization — and the central role that an independent partner like RUF plays in making that commitment operational.

RUF is uniquely qualified to perform these services by virtue of its statutory FDA-specific mandate, organizational independence, established relationships with the relevant stakeholder communities across all project areas, and demonstrated operational infrastructure for executing complex, multi-stakeholder engagements. No other organization combines these attributes in a manner suited to the breadth and sensitivity of the work described in this SOW.

SECTION 2 — OBJECTIVE

The objective of this contract is to engage the Reagan-Udall Foundation for the FDA to provide independent stakeholder convening, scientific engagement, operational evaluation, research, and report preparation services in support of FDA's regulatory science and public health mission across eleven (11) discrete project requirements spanning multiple FDA Centers and Offices.

Across all requirements, the Contractor shall:

- Facilitate evidence-based dialogue among diverse stakeholders — including regulated industry, academia, patient advocacy organizations, healthcare providers, state and federal partners, and the public — in a neutral, independent forum;
- Produce publicly available or agency-facing reports, white papers, meeting summaries, and recommendations that inform FDA's regulatory science priorities, policy development, and program operations;
- Leverage RUF's independence, credibility, and established stakeholder networks to generate outputs with broad legitimacy and public trust, consistent with FDA's commitment to transparency and scientific integrity;
- Advance FDA, HHS, and Administration priorities including regulatory transparency, innovation acceleration, product safety, rare disease, consumer protection, and the Make America Healthy Again (MAHA) agenda; and
- Ensure all public-facing materials include clear disclaimers distinguishing Contractor outputs from official FDA guidance, regulatory determinations, or policy positions.

SECTION 3 — SPECIFIC REQUIREMENTS AND TASKS

Each requirement below is independent and constitutes a discrete scope of work with its own tasks, deliverables, timeline, and estimated funding. The Contractor shall coordinate with the designated FDA Subject Matter Expert(s) (SMEs) and Contracting Officer's Representative (COR) for each requirement. Draft deliverables shall be submitted to the COR for review and comment prior to finalization. The Government shall have fifteen (15) business days to review and provide written comments on draft deliverables unless otherwise specified.

REQUIREMENT 1: Research Roundtable on the Development of Transcranial Ultrasound for Neurological and Psychiatric Applications

3.1.1 Objective

To organize and facilitate a public hybrid workshop that shares scientific information, clinical experiences, and technology developments related to transcranial ultrasound and builds consensus around safety parameters and data reporting requirements for neurological and psychiatric applications.

3.1.2 Specific Tasks

- Task 1.1 – Pre-Event Coordination: Coordinate with FDA (CDRH/OHT5 and OSEL), FUSF, and ITRUSST to finalize the workshop agenda, speaker roster, and logistical arrangements for a hybrid event at Hilton McLean Tysons Corner, McLean, Virginia, scheduled for November 10, 2026, co-located with the Focused Ultrasound Foundation's "20 Years of Curing with Sound" event (November 11–13, 2026).
- Task 1.2 – Survey Development and Administration Plan: Design, develop, and administer consensus-building surveys in advance of and during the workshop. Submit a written survey administration plan to FDA no later than November 3, 2026.
- Task 1.3 – Workshop Facilitation: Facilitate the public hybrid workshop (~200 in-person attendees; additional remote participants), including panel discussions on: (a) Neuromodulation — mechanism of action, safety parameters, clinical understanding, significant risk determination, consensus on definitions for therapeutic use, and pediatric population considerations; and (b) BBB Opening — mechanism of action, safety parameters, drug pairing and combination product considerations, liquid biopsy applications, oncology applications, and pediatric population considerations.
- Task 1.4 – Public Resource Website: Develop and maintain a publicly accessible website hosting recordings, slide decks, and transcripts from the event. All materials shall include clear disclaimers distinguishing workshop outputs from official FDA positions.
- Task 1.5 – White Paper / Final Report: Analyze survey data and workshop discussion outcomes and produce a White Paper documenting results. Submit the final report to FDA by May 10, 2027.

REQUIREMENT 2: Rare Disease Diagnostics Roundtable — Bridging Gaps in Rare Disease Diagnostics to Reduce the Diagnostic Odyssey

3.2.1 Objective

To explore unmet diagnostic needs across two rare disease clinical areas by convening a one-day private roundtable with a curated group of stakeholders following a structured pre-work phase, and to produce a roundtable report capturing key findings and recommendations.

3.2.2 Specific Tasks

- Task 2.1 – Pre-Work / Stakeholder Survey: Solicit written feedback from a broad range of stakeholders — including patients, advocates, clinicians, researchers, and industry representatives — on unmet diagnostic needs in two designated rare disease clinical areas. Compile and analyze written input for use at the roundtable.
- Task 2.2 – Participant Identification and Invitation: In coordination with CDRH SMEs, identify and invite a curated group of stakeholders for the private roundtable, ensuring representation from patients and advocates, rare disease clinicians, researchers, and industry.
- Task 2.3 – Roundtable Facilitation: Facilitate a one-day private roundtable discussion on October 28 or 29, 2026, focused on identifying and prioritizing unmet diagnostic needs and potential solutions across the two designated clinical areas.
- Task 2.4 – Roundtable Report: Prepare and publish a roundtable report summarizing key discussions, areas of consensus, identified gaps, and recommendations. Submit draft to FDA for review prior to finalization.

REQUIREMENT 3: Medical Device Real-World Evidence Transparency and Quality Throughout the Data Lifecycle from Point-of-Care to Evidence Generation

3.3.1 Objective

To convene a one-day private roundtable of senior FDA staff and curated key opinion leaders (KOLs) working toward alignment on: (1) a lifecycle reference model; (2) a data provenance "quality label" that travels with data; (3) a minimum common layer of metrics; and (4) an accountability model anchored on pre-exchange transparency across the full RWD pipeline.

3.3.2 Specific Tasks

- Task 3.1 – Participant Identification and Pre-Circulated Discussion Frameworks: Identify and invite KOLs spanning clinical informatics, regulatory science, biostatistics, epidemiology, and EHR operations. Develop and distribute structured pre-circulated discussion frameworks to focus deliberations at least two weeks prior to the roundtable.
- Task 3.2 – Roundtable Facilitation: Facilitate the one-day closed roundtable covering: (a) point-of-care data collection variability and foundational data gaps; (b) EHR interoperability and FHIR configuration challenges; (c) harmonization-stage completeness metrics and vocabulary translation errors; and (d) end-to-end data provenance documentation standards and fit-for-purpose validation frameworks.
- Task 3.3 – Summary Whitepaper: Develop a publicly available summary whitepaper documenting roundtable outcomes, consensus positions, and identified gaps.
- Task 3.4 – Structured Gap Analysis: Produce a structured gap analysis identifying areas where standardized completeness thresholds and fit-for-purpose validation frameworks are lacking across the RWD pipeline.
- Task 3.5 – Working Project Charter: Develop a working project charter for actionable follow-on activities targeting Q2–Q4 2027 milestones, including pre-identified pilot partners and budget contingency parameters.

REQUIREMENT 4: Neurological Innovation Assessment Initiatives (NeuroAdvance Initiative)

3.4.1 Objective

To convene stakeholders to: (1) advance biomarker development, surrogate endpoint validation, and innovative clinical trial designs aligned with patient-focused drug development principles; and (2) support a structured cross-center review across CBER, CDER, and CDRH to assess neurological disease innovation pipelines, identify strategic gaps, prioritize high-impact regulatory science questions, and clarify evidentiary standards needed to demonstrate meaningful clinical impact.

3.4.2 Specific Tasks

- Task 4.1 – Stakeholder Convening: Organize and facilitate a stakeholder convening (meeting or workshop) bringing together FDA staff, industry representatives, academic researchers, patient advocates, and other relevant stakeholders.
- Task 4.2 – Gap and Priority Analysis: Develop a structured summary identifying strategic gaps in the neurological innovation pipeline and prioritized regulatory science questions requiring further attention.
- Task 4.3 – Recommendations Report: Prepare a written report capturing stakeholder input, key findings, and actionable recommendations to advance biomarker development, surrogate endpoint validation, and innovative trial design.
- Task 4.4 – Cross-Center Coordination Framework: Document a coordinated cross-center review approach across CBER, CDER, and CDRH to support ongoing assessment of neurological disease innovation pipelines.

REQUIREMENT 5: Cosmetics — Adverse Event Signals and Consumer Awareness

3.5.1 Objective

To explore adverse event signals from publicly available data sources and compare them with FDA cosmetic adverse event data; and to investigate consumer awareness of FDA's role in regulating cosmetics to identify avenues for consumer education, in support of an FDA cosmetovigilance program aligned with MoCRA and the MAHA agenda.

3.5.2 Specific Tasks

- Task 5.1 – Adverse Event Taxonomy Development: Develop a standardized adverse event taxonomy covering rash, redness, burns, hair loss, irritation, infection, headache, scarring, allergic reactions, contamination, and related events to build consistency in review across data sources.
- Task 5.2 – Data Collection and Signal Analysis (Year 1): Collect and analyze publicly available data from major retailers and social media platforms over a defined time period. Benchmark review-derived adverse event signals against FDA cosmetic adverse event data. Follow applicable site terms of service and focus on de-identified data. Frame results as signal detection rather than medical or causal conclusions.
- Task 5.3 – Consumer Polling and/or Focus Groups: Conduct supplemental consumer polling and/or focus groups to determine: (a) which data sources consumers use most; (b) consumer knowledge about FDA regulation of cosmetics; and (c) consumer awareness of adverse event reporting options. Obtain IRB consultation as appropriate.
- Task 5.4 – Slide Deck Deliverables: Prepare slide decks detailing findings from each round of data analysis, including a comparative assessment of platforms, information quality, and practices.
- Task 5.5 – Reproducible Workflow and Adverse Event Dashboard: Develop a reproducible data scraping and analysis workflow and an adverse event dashboard for ongoing signal monitoring.

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- Task 5.6 – Manuscript Preparation (Optional): Consider preparation of a journal article on findings for co-publication by FDA and RUF authors, subject to FDA review and clearance.

REQUIREMENT 6: Generic Drug Quality Testing Stakeholder Convening

3.6.1 Objective

To convene a moderated public workshop and private roundtable on generic drug quality and the role of third-party testing, grounding the conversation in science and evidence, and generating a white paper summarizing key themes, stakeholder input, and potential recommendations to address public perception gaps and identify opportunities for constructive collaboration.

3.6.2 Specific Tasks

- Task 6.1 – Private Roundtable (October – November 2026): Convene an invitation-only, moderated roundtable with federal partners, industry stakeholders, and healthcare organizations to explore concerns around generic drug quality, existing testing practices, and collaboration opportunities. Incorporate advanced pre-roundtable polling as appropriate.
- Task 6.2 – Public Workshop (December 2026 – January 2027): Convene a public meeting at which participants discuss available data on generic drug quality and approaches for potential improvements to the existing quality framework, including quality requirements for generic drug applicants, FDA inspections and surveillance, and the role, validity, and evidentiary value of third-party testing methodologies relative to FDA-validated and compendial standards.
- Task 6.3 – White Paper (February 2027): Develop and publish a publicly available meeting report summarizing: (a) key themes and areas of consensus or disagreement; (b) potential recommendations for further research, pilot programs, or targeted communication strategies; (c) a structured, evidence-based assessment of proposed framework changes and third-party testing methodologies; and (d) identification of areas for constructive collaboration.

REQUIREMENT 7: CBER–CDER Educational Workshop (Rare Disease Innovation Hub)

3.7.1 Objective

To host a public educational workshop explaining regulatory differences between CBER and CDER related to product type for rare disease products, and to create discrete educational video modules for ongoing public use on the Rare Disease Innovation Hub webpage.

3.7.2 Specific Tasks

- Task 7.1 – Workshop Planning and Logistics: In coordination with the RDIH and FDA SME, plan and organize a public educational workshop covering: (a) types of products regulated by each center; (b) differences in effect size and mechanism of action; and (c) expectations with regard to trial design and supportive evidence for rare disease products.
- Task 7.2 – Workshop Facilitation: Facilitate the public workshop, ensuring balanced and transparent presentation of each center's regulatory approach. The workshop shall serve as a resource for both industry and disease advocates.
- Task 7.3 – Educational Video Module Production: Following the workshop, produce discrete educational video modules based on session topics for public posting on the Rare Disease Innovation Hub webpage.

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REQUIREMENT 8: Rare Disease Innovation Hub Meetings

3.8.1 Objective

To facilitate two substantive meetings and two virtual listening sessions in support of an ongoing rare disease regulatory project conducted in partnership with the Office of the Commissioner, including pre-work preparation and post-engagement reporting for each meeting.

3.8.2 Specific Tasks

- Task 8.1 – Meeting 1 Pre-Work: Conduct preparatory activities for Meeting 1, including participant identification, agenda development, background materials preparation, and coordination with RDIH and the Office of the Commissioner.
- Task 8.2 – Meeting 1 Facilitation: Facilitate the first substantive meeting.
- Task 8.3 – Meeting 1 Post-Engagement Report: Prepare and deliver a post-engagement report or paper summarizing Meeting 1 outcomes, key themes, and findings.
- Task 8.4 – Meeting 2 Pre-Work, Facilitation, and Post-Engagement Report: Complete the same scope of pre-work, facilitation, and post-engagement reporting for Meeting 2.
- Task 8.5 – Virtual Listening Session 1: Facilitate a virtual listening session with stakeholder input documentation.
- Task 8.6 – Virtual Listening Session 2: Facilitate a second virtual listening session with stakeholder input documentation.

REQUIREMENT 9: FDA Human Foods Program — Accelerating FDA-State Integrated Inspections (Phase 1 and Phase 2)

3.9.1 Objective

Phase 1: To convene regulators, industry, consumer advocates, and state partners to define "success" criteria for an integrated federal-state inspection system, including regulatory performance expectations, industry compliance, consumer confidence, and public health outcomes. Phase 2: To convene an expert panel to develop system performance metrics and data needs, compare integrated state inspection results, and produce a final report with recommendations and an economic case for the integrated model.

3.9.2 Specific Tasks

- Task 9.1 – Backgrounder / Literature Review (Phase 1, commencing August 2026): Prepare a backgrounder with literature review and cross-regulatory analysis describing the inspectional shift for stakeholders.
- Task 9.2 – Stakeholder Interviews (Phase 1, September–November 2026): Conduct interviews to gather industry perspectives and identify roundtable participants and subject matter experts.
- Task 9.3 – Virtual Roundtables (Phase 1, September–November 2026): Convene up to four (4) stakeholder roundtables virtually in coordination with HFP and the Partnership for Food Protection. Prepare a written summary of each roundtable for participants and FDA.
- Task 9.4 – Public Hybrid Meeting (Phase 1, tentatively January 2027): Conduct a hybrid public meeting sharing learnings and inviting public comment. Post recording and transcript publicly on the Foundation's website. Compile public comments and cross-sector themes.
- Task 9.5 – Phase 1 Final Report and Slide Deck (by early March 2027): Publish a final Phase 1 report and submit a detailed slide deck summarizing all stakeholder input to FDA.

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- Task 9.6 – Phase 2 Expert Panel and Metrics Development: Convene an expert panel to develop performance metrics and data needs for the integrated federal-state inspection system and compare results of states in the system.
- Task 9.7 – Phase 2 Final Report: Deliver a comprehensive final report with: (a) recommendations for inspection system performance metrics; (b) guidance on how metrics should be designed, tracked, and shared; and (c) a defensible economic case for prevention-based inspections.

REQUIREMENT 10: Cosmetics Risk-Based Inspection Strategic Plan

3.10.1 Objective

To assist the Office of Cosmetics and Colors in creating the strategic structure for a MoCRA-compliant cosmetics inspectional program through a multi-phase process of internal information gathering, expert panel analysis, and strategic planning report development.

3.10.2 Specific Tasks

- Task 10.1 – Phase 1: Internal Information Collection: (a) Meet with OCS Regulatory Policy and Compliance Team to review existing practices; (b) conduct a review of successful strategies employed by other regulatory inspection programs; (c) facilitate internal roundtables with FDA staff; (d) open an internal portal for FDA team members to provide written feedback; (e) interview approximately 6–8 regulated industry representatives with a focus on those already subject to drug inspections; and (f) draft a plan for Phase 2 external information gathering.
- Task 10.2 – Phase 1 Summary Deliverable: Compile findings into a summary slide deck or comparable document presenting successful and unsuccessful experiences from other inspection programs and expectations, concerns, and questions from regulated industry. Submit to FDA for review.
- Task 10.3 – Phase 2: Expert Panel Analysis: (a) Establish an expert panel to review Phase 1 information and identify potential operational approaches; (b) develop potential frameworks for testing, piloting, and refining concepts; and (c) gather and analyze external information through interviews, listening sessions, roundtable discussions, public meetings, and/or a written public comment portal.
- Task 10.4 – Phase 2 Comprehensive Strategic Report: Prepare a comprehensive report for OCS presenting detailed analysis of potential operational approaches, including considerations for rollout, risk-based prioritization, and stakeholder education, to inform OCS's strategic inspection plan.

REQUIREMENT 11: Nicotine Use Disorder — Prescribe with Confidence, NRT NDA Stakeholder Interviews, and Public Meeting on Nicotine Use Disorder

3.11.1 Objective

To support three complementary engagement activities: (1) a "Prescribe with Confidence" initiative to increase healthcare provider confidence in recommending FDA-approved NUD treatments; (2) structured stakeholder interviews related to nicotine replacement therapy new drug applications; and (3) a public meeting on nicotine use disorder to advance the NUD policy and regulatory science agenda.

3.11.2 Specific Tasks

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- Task 11.1 – Prescribe with Confidence (PwC) Initiative: Design and implement engagement activities — which may include educational convenings, stakeholder forums, and/or resource development — to increase healthcare provider confidence in prescribing FDA-approved NUD treatments. Coordinate with CDER SMEs on content and scientific accuracy throughout.
- Task 11.2 – NRT NDA Stakeholder Interviews: Conduct structured interviews with stakeholders relevant to nicotine replacement therapy new drug applications. Compile and analyze interview findings and submit a written summary report to FDA.
- Task 11.3 – Public Meeting on Nicotine Use Disorder: Plan, organize, and facilitate a public meeting on NUD, covering the regulatory science landscape, available treatment options, barriers to access, and opportunities for innovation. Coordinate agenda and speaker selection with CDER SMEs.
- Task 11.4 – Post-Meeting Report: Deliver a comprehensive summary report of the public meeting to FDA, including key findings, areas of consensus or disagreement, and actionable recommendations.

REQUIREMENT 12: Alcohol Use Disorder — Patient and Provider Listening Sessions on Pharmacotherapy and Unmet Needs

3.12.1 Objective

To gather structured, firsthand perspectives from patients, caregivers, and clinicians on barriers and unmet needs in alcohol use disorder (AUD) treatment through a series of RUF-convened listening sessions. Findings will inform FDA's regulatory and scientific priorities related to AUD pharmacotherapy development, clinical endpoints, and labeling.

3.12.2 Specific Tasks

Task 12.1 – Session Design and Planning: Develop session protocols, structured discussion guides, and targeted recruitment strategies for both patient/caregiver and clinician populations. Plan sessions to address six critical domains: awareness of FDA-approved medications, access barriers, perceived efficacy, treatment complexity, real-world use, and tolerability — including among patients with co-occurring conditions.

Task 12.2 – Patient Listening Sessions: Convene a minimum of three structured listening sessions with AUD patients and caregivers to gather qualitative input across the six domains identified above. Ensure diverse representation across AUD severity, demographic backgrounds, and comorbidity profiles. Coordinate with patient advocacy organizations, treatment centers, and community groups to support recruitment and reduce participation barriers.

Task 12.3 – Provider Listening Sessions: Convene a minimum of two structured listening sessions with clinicians to gather perspectives on prescribing barriers, perceptions of treatment efficacy, and opportunities for individualized and precision medicine approaches in AUD treatment.

Task 12.4 – Data Synthesis and Analysis: Conduct thematic analysis across all sessions to identify convergent and divergent perspectives on treatment gaps, unmet needs, and drug development priorities. Ensure findings reflect the heterogeneous AUD population.

Task 12.5 – Summary Report: Produce a publicly available written report synthesizing findings across all sessions to inform CDER's regulatory and scientific priorities, including insights into clinical endpoints, drug labeling, and new drug development opportunities. Disseminate findings to CDER, other relevant HHS agencies, and professional associations. Coordinate with CDER SMEs throughout.

REQUIREMENT 13: Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) — REMS Landscape Review and Stakeholder Interviews

3.13.1 Objective

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To assess the current landscape of the Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) Risk Evaluation and Mitigation Strategy (REMS) by: (1) evaluating the extent to which REMS safety information overlaps with existing publicly available resources and healthcare provider education infrastructure; and (2) identifying any remaining care gaps in the safe use of BTOD products. Findings will inform potential future modifications to the BTOD REMS in light of significant changes to the healthcare landscape since the REMS was first approved.

3.13.2 Specific Tasks

- Task 13.1 – Evidence and Landscape Review: Conduct a systematic review of state requirements governing BTOD prescribing and dispensing, state-level Prescription Drug Monitoring Program (PDMP) requirements, relevant clinical practice guidelines, DEA-required training requirements, and other publicly available educational resources. Assess the degree to which information covered under the BTOD REMS overlaps with existing state laws, publicly available resources, and healthcare provider education infrastructure (e.g., medical school curricula, residency training).
- Task 13.2 – Stakeholder Interviews and Focus Groups: Engage with healthcare providers — including prescribers and pharmacists — to gather structured perspectives on their knowledge and awareness of the serious risks of BTOD and the safe use conditions outlined in the REMS materials. Identify where knowledge gaps or care gaps remain.
- Task 13.3 – Summary Report: Compile and analyze findings from the landscape review and stakeholder engagement activities into a written report for FDA. The report should identify areas of overlap between the REMS and existing infrastructure, remaining care gaps, and recommendations to inform potential REMS modifications. Coordinate with CDER SMEs throughout.

REQUIREMENT 14: Pediatric Unintentional Exposure to MOUD — Messaging Campaign Toolkit and Dissemination

3.14.1 Objective

To develop a scalable education program for consumers and healthcare professionals aimed at reducing the risk of pediatric unintentional exposure (PUE) to medications for opioid use disorder (MOUD), including buprenorphine-containing products for opioid dependence (BTODs) and methadone. This requirement builds upon a prior RUF project that identified knowledge gaps and developed evidence-based message frameworks; the current effort will translate those frameworks into a disseminable toolkit and structured distribution plan.

3.14.2 Specific Tasks

- Task 14.1 – Educational Toolkit Development: Develop a comprehensive educational toolkit based on previously tested message frameworks addressing safe storage of MOUD and emergency response for caregivers and patients. The toolkit shall include message frameworks, recommendations for audience-specific message tailoring, and impactful visuals and infographics. Content and messaging shall be reviewed for scientific accuracy and clinical appropriateness in coordination with CDER SMEs, and shall be designed to avoid contributing to stigma toward individuals with substance use disorders or adversely affecting patient access to MOUD.
- Task 14.2 – Distribution Plan: Develop a structured distribution plan for broad dissemination of the toolkit. The plan shall identify priority outreach channels and audiences, including federal partners, national and state professional organizations, local community organizations, and

other trusted messengers. The plan shall also evaluate the feasibility of a publicly accessible web-based platform for toolkit hosting.

- Task 14.3 – Dissemination Activities: Implement dissemination activities in accordance with the approved plan, which may include webinars, workshops, roundtables, or other outreach events as appropriate. Coordinate with CDER SMEs on content accuracy and messaging throughout implementation

REQUIREMENT 15: Cannabis Public Health Message Testing

3.15.1 Objective

To develop an evidence-based public health messaging framework for cannabis products through structured stakeholder engagement, message testing, and synthesis of findings into actionable communications recommendations for FDA and HHS. The initiative will address information needs for the general public and healthcare providers (HCPs) related to cannabis product formulations, potency, manufacturing, and health impacts — with particular focus on vulnerable populations such as adolescents, young adults, pregnant and breastfeeding women, and the elderly.

3.11.2 Specific Tasks

- Task 15.1 – Listening Sessions and Stakeholder Interviews (Public): Conduct listening sessions and focus groups with members of the public to identify areas of confusion and information needs regarding cannabis products. Explore consumer beliefs and assumptions (e.g., perceptions that natural products are inherently safe, or that FDA regulates all cannabis products) that may contribute to public health risk.
- Task 15.2 – Listening Sessions and Stakeholder Interviews (Healthcare Providers): Conduct listening sessions and interviews with HCPs to identify areas of concern, gaps in available information, and preferred communication tools and formats (e.g., one-pagers, clinical decision aids) for patient counseling. Assess HCP needs for continuing education on cannabis-related topics.
- Task 15.3 – Message Framework Development: Prioritize public health communication topics based on stakeholder input. Draft candidate messages for both public and HCP audiences and conduct message testing to assess effectiveness, clarity, and potential for unintended consequences. Refine messages based on testing results.
- Task 15.4 – White Paper and Communications Report: Produce a written report summarizing findings from all stakeholder engagement and message testing activities. The report shall propose potential communications strategies and a framework for FDA and HHS to consider implementing. Coordinate with CDER SMEs throughout

REQUIREMENT 16: Drug Repurposing Accelerator

3.16.1 Objective

To convene a rapid-cycle, stakeholder-driven meeting series — the "Drug Repurposing Accelerator" — designed to advance the field of drug repurposing by working through key operational and strategic challenges in a shared-learning format. The series will produce publicly available meeting summaries and a regulatory roadmap for a reproducible, scalable, and predictable pathway for drug repurposing, informed by input from researchers, clinicians, patient groups, industry, and federal partners.

3.16.2 Specific Tasks

- Task 16.1 – Meeting Series Design and Planning: In collaboration with CDER SMEs, develop the discussion agenda, identify and recruit speakers and participants, and finalize questions and topics for each session. Participants shall be drawn from a variety of sectors including federal partners, regulated industry, academia, non-profits, health insurers, and healthcare providers. All invited participants shall be encouraged to attend the full series to promote continuity of discussion across sessions.
- Task 16.2 – Drug Repurposing Accelerator Meeting Series: Convene approximately 11 one-hour virtual, invitation-only meetings over a six-month period (November 2026 through April 2027), held on a biweekly basis (with one meeting in December). Each session shall feature one to two primary speakers and provide ample opportunity for interactive discussion among participants.
- Task 16.3 – Individual Meeting Summaries: Following each session, prepare and publicly post a brief summary of the meeting's discussion and key takeaways on the RUF website.
- Task 16.4 – Final Meeting Series Summary: Upon conclusion of the meeting series, produce a comprehensive written summary synthesizing key themes, expert perspectives, and stakeholder input from across all sessions.
- Task 16.5 – Drug Repurposing Regulatory Roadmap: Using the totality of discussions from the meeting series, develop and publish a regulatory roadmap clearly illustrating a reproducible, scalable, and predictable regulatory pathway for drug repurposing, vetted with FDA.

SECTION 4 — Deliverables

4.1 Format of Deliverables

Electronic copies must be in a format compatible with Office 365 and Adobe Acrobat (version 10 or later). Documents will be required to be Section 508 compliant. Weekly, interim, informal, and working-copy products may be provided by e-mail to the COR.

Final electronic copies of deliverables must be in a format compatible with Office 365 and Adobe Acrobat (version 10 or later).

4.2 Deliverables Submission Procedure

The Contractor shall submit all deliverables to the COR, unless otherwise stated. The COR will be responsible for the review of all draft and final deliverables to ensure accuracy, functionality, completeness, professional quality, and overall compliance with the guidelines requirements of the task.

The Contractor shall ensure the accuracy and completeness of all deliverables in accordance with referenced policy, regulations, laws, and directives. Reports and presentations shall be concise and clearly written; errors, misleading or unclear statements, incomplete or irrelevant information, and/or excessive rhetoric, repetition, and "padding," or excessive length if a page limit is imposed, shall be considered deficiencies and will be subject to correction by the Contractor at no additional cost to the government. Unless specified otherwise, the government shall have fifteen (15) working days to complete the review and approve the deliverables.

If deficiencies are found or areas require modification, the Contractor will be notified and shall have five (5) calendar days to correct the deficiencies. Upon re-submission by the Contractor, the government will reapply the same acceptance criteria. If the deliverable does not meet the acceptance criteria a second

time, the government may consider the Contractor as having deficient performance with respect to the subject task.

4.3 Summary of Deliverables

TASK	DELIVERABLES	DESCRIPTION	DUE DATE
N/A	Quarterly Progress Reporting	Reports summarizing activities completed, Deliverables submitted, upcoming milestones, expenditures to date, and any risks or issues requiring Government attention	Quarterly
3.1.2	Survey Administration Plan	Written plan for survey design and delivery to workshop participants	November 3, 2026
3.1.2	Workshop Event	Hybrid public workshop on transcranial ultrasound technologies	November 10, 2026
3.1.2	Survey Data Collection Summary	Compiled survey responses and preliminary analysis shared with FDA	TBD post-event
3.1.2	Public Resource Website	Hosted recordings, transcripts, and slide decks with required disclaimers	Within 30 days post-event
3.1.2	White Paper / Final Report	Publicly available report documenting workshop and survey outcomes submitted to FDA	May 10, 2027
3.2.2	Pre-Work Stakeholder Feedback Summary	Written summary of pre-roundtable survey/feedback submitted to FDA	Prior to roundtable
3.2.2	Private Roundtable Event	One-day facilitated private roundtable with curated stakeholders	October 28–29, 2026
3.2.2	Roundtable Report	Written report documenting discussions, findings, gaps, and recommendations	Within 60 days post-event
3.3.2	Pre-Circulated Discussion Frameworks	Structured facilitation materials distributed to participants prior to roundtable	At least 2 weeks pre-event
3.3.2	Private Roundtable Event	One-day closed roundtable with senior FDA staff and invited KOLs	Q1–Q2 FY2027
3.3.2	Summary Whitepaper	Publicly available report documenting roundtable consensus and key findings	Within 60 days post-event
3.3.2	Structured Gap Analysis	Document identifying gaps in RWD pipeline standards, completeness, and provenance documentation	Within 60 days post-event
3.3.2	Working Project Charter	Charter scoping follow-on pilot activities with milestones and risk mitigation	Within 90 days post-event
3.4.2	Stakeholder Convening(s)	Meeting or workshop with FDA and external stakeholders on neurological innovation	Within 6 months of award

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3.4.2	Gap and Priority Analysis	Structured summary of pipeline gaps and priority regulatory science questions	Within 6 months of award
3.4.2	Recommendations Report	Written report with stakeholder input and actionable recommendations	Within 6 months of award
3.4.2	Cross-Center Coordination Framework	Documentation of coordinated review approach across CBER, CDER, and CDRH	Within 6 months of award
3.5.2	Adverse Event Taxonomy	Standardized taxonomy of cosmetic adverse events for cross-platform use	Within 60 days of award
3.5.2	Year 1 Data Analysis Slide Decks	Slide decks presenting signal findings, platform comparison, and FDA data benchmarking	9/29/2027
3.5.2	Consumer Polling / Focus Group Report	Summary of consumer awareness findings on cosmetics safety and FDA regulation	9/29/2027
3.5.2	Reproducible Workflow / Dashboard	Data scraping and analysis workflow and adverse event monitoring dashboard	9/29/2027
3.5.2	Draft Manuscript (Optional)	Co-authored journal article draft for FDA review and clearance	TBD (if pursued)
3.6.2	Private Roundtable	Invitation-only moderated roundtable on generic drug quality and third-party testing	October – November 2026
3.6.2	Public Workshop	Open public workshop on generic drug quality framework and testing methodologies	December 2026 – January 2027
3.6.2	White Paper / Report	Publicly available report with findings, consensus positions, and recommendations	February 2027
3.7.2	CBER–CDER Public Educational Workshop	Public workshop on CBER and CDER regulatory approach differences for rare disease products	Within 12 months of award
3.7.2	Educational Video Modules	Discrete recorded modules by session topic posted publicly on the RDIH webpage	Within 60 days post-workshop
3.8.2	Meeting 1 Pre-Work Materials	Background materials, agenda, and participant list for Meeting 1	Prior to Meeting 1
3.8.2	Meeting 1 Facilitation	Facilitated substantive meeting with stakeholders	TBD per project schedule
3.8.2	Meeting 1 Post-Engagement Report	Written report or paper summarizing Meeting 1 outcomes	Within 45 days post-meeting
3.8.2	Meeting 2 Pre-Work Materials	Background materials, agenda, and participant list for Meeting 2	Prior to Meeting 2
3.8.2	Meeting 2 Facilitation	Facilitated substantive meeting with stakeholders	TBD per project schedule
3.8.2	Meeting 2 Post-Engagement Report	Written report or paper summarizing Meeting 2 outcomes	Within 45 days post-meeting
3.8.2	Virtual Listening Session 1	Facilitated virtual listening session with stakeholder input documentation	TBD per project schedule

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3.8.2	Virtual Listening Session 2	Facilitated virtual listening session with stakeholder input documentation	TBD per project schedule
3.9.2	Backgrounder / Literature Review	Cross-regulatory analysis backgrounder for stakeholders	Late October 2026
3.9.2	Interview Summary	Summary of industry perspectives and identified SMEs and roundtable participants	October – December 2026
3.9.2	Roundtable Summaries (up to 4)	Written summaries of each virtual roundtable for participants and FDA	October – December 2026
3.9.2	Public Meeting Recording and Transcript	Posted recording, transcript, and compiled public comments	February 2027
3.9.2	Phase 1 Final Report	Published Phase 1 final report with cross-sector themes and recommendations	Early April 2027
3.9.2	Phase 1 FDA Slide Deck	Detailed slide deck summarizing all stakeholder input submitted to FDA	Early April 2027
3.9.2	Phase 2 Expert Panel Convening	Expert panel meetings for metrics development and inspection system comparison	TBD per Phase 2 schedule
3.9.2	Phase 2 Final Report	Comprehensive final report with metrics, tracking guidance, and economic case	TBD per Phase 2 schedule
3.10.2	Phase 1 Findings Slide Deck / Report	Summary of internal and industry information, lessons learned, and concerns from other programs	End of Phase 1
3.10.2	Phase 2 Engagement Plan	Plan for external information gathering activities in Phase 2	End of Phase 1
3.10.2	Expert Panel Convening	Expert panel review of Phase 1 findings and identification of operational framework options	Phase 2
3.10.2	Phase 2 Comprehensive Strategic Report	Detailed report informing OCS cosmetics inspectional strategic plan	End of Phase 2
3.11.2	PwC Initiative Materials / Report	Documentation of PwC engagement activities and outcomes submitted to FDA	TBD per project schedule
3.11.2	NRT NDA Interview Summary Report	Written summary of structured stakeholder interviews submitted to FDA	TBD per project schedule
3.11.2	NUD Public Meeting	Facilitated public meeting on nicotine use disorder	TBD per project schedule
3.11.2	Public Meeting Post-Meeting Report	Comprehensive report on meeting findings, themes, and recommendations	Within 60 days post-meeting
3.12.2	AUD Listening Session Protocols and Discussion Guides	Finalized session protocols, structured discussion guides, and recruitment strategies for patient/caregiver and provider listening sessions	TBD per project schedule
3.12.2	Patient Listening Session Proceedings	Documented proceedings from a minimum of three structured listening sessions with AUD patients and caregivers	TBD per project schedule

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3.12.2	Provider Listening Session Proceedings	Documented proceedings from a minimum of two structured listening sessions with clinicians on AUD prescribing barriers and treatment perspectives	TBD per project schedule
3.12.2	AUD Listening Sessions Summary Report	Publicly available written report synthesizing thematic findings across all listening sessions to inform CDER regulatory and scientific priorities	TBD per project schedule
3.13.2	BTOD REMS Evidence and Landscape Review	Written review of state BTOD prescribing and dispensing requirements, PDMP requirements, guidelines, and other publicly available resources; assessment of overlap with existing REMS safety information	TBD per project schedule
3.13.2	BTOD REMS Stakeholder Interview and Focus Group Proceedings	Documentation of structured interviews and focus groups with prescribers and pharmacists on knowledge and awareness of BTOD REMS safe use conditions	TBD per project schedule
3.13.2	BTOD REMS Landscape Review Summary Report	Comprehensive written report identifying areas of overlap between the BTOD REMS and existing healthcare infrastructure, remaining care gaps, and recommendations to inform potential REMS modifications	TBD per project schedule
3.14.2	PUE Educational Toolkit	Comprehensive educational toolkit including evidence-based message frameworks, audience-specific tailoring recommendations, and visuals/infographics for consumers and healthcare professionals on safe storage and emergency response for MOUD	TBD per project schedule
3.14.2	PUE Dissemination Plan	Structured distribution plan identifying priority outreach channels, target audiences, and assessment of web-based platform feasibility for toolkit hosting	TBD per project schedule
3.14.2	PUE Dissemination Activities Report	Summary documentation of dissemination activities conducted (e.g., webinars, workshops, roundtables) and reach/engagement outcomes	TBD per project schedule
3.15.2	Cannabis Stakeholder Listening Session Proceedings (Public)	Documented findings from listening sessions and focus groups with members of the public on cannabis product information needs, confusion areas, and consumer beliefs	TBD per project schedule
3.15.2	Cannabis Stakeholder Listening Session Proceedings (HCPs)	Documented findings from listening sessions and interviews with healthcare providers on information gaps, patient counseling needs, and preferred communication tools	TBD per project schedule
3.15.2	Cannabis Message Framework	Prioritized public health communication topics and tested candidate messages for public and HCP audiences, refined based on message testing results	TBD per project schedule
3.15.2	Cannabis Message Testing White	Written report summarizing all stakeholder engagement and message testing findings with	TBD per project schedule

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	Paper / Communications Report	proposed communications strategies and framework for FDA and HHS consideration	
3.16.2	Drug Repurposing Accelerator Meeting Summaries	Individual public summaries for each of the approximately 11 virtual stakeholder meetings, posted on the RUF website following each session (November 2026 – April 2027)	Following each meeting (Nov 2026 – Apr 2027)
3.16.2	Drug Repurposing Accelerator Final Meeting Series Summary	Comprehensive written summary of the full Drug Repurposing Accelerator meeting series, synthesizing key themes, expert perspectives, and stakeholder input	April 2027
3.16.2	Drug Repurposing Regulatory Roadmap	Published roadmap illustrating a reproducible, scalable, and predictable regulatory pathway for drug repurposing, vetted with FDA and informed by the full meeting series	April 2027

SECTION 4 – CONTRACT TYPE

The contract is Firm Fixed Price.

SECTION 5 – PERIOD OF PERFORMANCE

The Period of Performance for this contract shall be from September 30, 2026 through September 29, 2027, unless extended by mutual written agreement. Individual requirements may have distinct performance periods as specified in Section 3. The Contractor shall not incur costs beyond the funded ceiling for each requirement without prior written approval from the Contracting Officer.

SECTION 6 – PLACE OF PERFORMANCE

Work will be performed at the Contractor's facility.

SECTION 7 – GOVERNMENT CONTACTS

Contracting Officer:
Name:
Telephone Number:
Email Address:

Contract Specialist:
Name:
Telephone Number:
Email Address:

Contracting Officer's Representative:
Name:
Telephone Number:

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Email Address:

SECTION 8 – SECTION 508 STANDARD REQUIREMENTS

- Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase information and communication technologies (ICT) that meet specific accessibility standards. This law helps to ensure that federal employees with disabilities have access to, and use of, the information and data they need to do their jobs. Furthermore, this law ensures that members of the public with disabilities have the ability to access government information and services.
- There are three regulations addressing the requirements detailed in Section 508. The Section 508 technical and functional standards are codified at 36 CFR Part 1194 and may be accessed through the Access Board's Web site at http://www.access-board.gov. The second regulation issued to implement Section 508 is the Federal Acquisition Regulation (FAR). FAR Part 39.2 requires that agency acquisitions of Electronic and Information Technology (EIT) comply with the Access Board's standards. The entire FAR is found at Chapter 1 of the Code of Federal Register (CFR) Title 48, located at http://www.acquisition.gov. The FAR rule implementing Section 508 can be found at http://www.section508.gov. The third applicable regulation is the HHS Acquisition Regulation (HHSAR).
- Regardless of format, all Web content or communications materials produced for publication on or delivery via HHS Web sites - including text, audio or video - must conform to applicable Section 508 standards to allow federal employees and members of the public with disabilities to access information that is comparable to information provided to persons without disabilities. All contractors (including subcontractors) or consultants responsible for preparing or posting content intended for use on an HHS-funded or HHS-managed Web site must comply with applicable Section 508 accessibility standards, and where applicable, those set forth in the referenced policy or standards documents below. Remediation of any materials that do not comply with the applicable provisions of 36 CFR Part 1194 as set forth in the SOW, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.
- Unless an agency exception to this requirement exists, the Contractor must conform to applicable Section 508 standards and must apply best practices associated with Section 508 compliance during the application design, development, and testing phases. The Contractor shall utilize FDA approved tools to verify the compliance with the Section 508 standards and ensure the delivery of the fully compliant products.
- The following Section 508 provisions apply to the content or communications material identified in this SOW:
- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)

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- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at https://www.hhs.gov/web/section-508/making-files-accessible/index.html, or from the Section 508 Coordinator listed at https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

SECTION 9 – SECURITY AND PRIVACY CONSIDERATIONS

I. Procurements Requiring Information Security and/or Physical Access Security

1. Baseline Security Requirements

a. Applicability. The requirements herein apply whether the entire contract or modification (hereafter "contract"), or portion thereof, includes either or both of the following:

i. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the FDA mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

b. Safeguarding Information and Information Systems. All government information and information systems must be protected in accordance with FDA policies and level of risk. At a minimum, the Contractor (and/or any subcontractor) must

i. Protect the:

- Confidentiality, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
- Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
- Availability, which means ensuring timely and reliable access to and use of information.

ii. Categorize all information owned and/or collected/managed on behalf of FDA and information systems that store, process, and/or transmit FDA information in accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories. Based on information provided by the System/Data Owner, ISSO, privacy representative, or other POC, the impact level for each Security Objective (Confidentiality, Integrity, and Availability) and the Overall Impact Level, which is the highest watermark of the three factors of the information or information system are the following:

(i) Confidentiality: ☐Low ☐Moderate ☐High

(ii) Integrity: ☐Low ☐Moderate ☐High

(iii) Availability: ☐Low ☐Moderate ☐High

(iv) Overall Impact Level: ☐Low ☐Moderate ☐High

iii. Based on the agreed-upon level of impact, implement the necessary safeguards to protect all information systems and information collected and/or managed on behalf of FDA regardless of location or purpose.

iv. Report any discovered or unanticipated threats or hazards by either the agency or contractor, or if existing safeguards have ceased to function immediately after discovery, within one (1) hour or less, to the government representative(s). This includes notifying the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) within one (1) hour of discovery/detection in the event of a cybersecurity or privacy incident.

v. Adopt and implement all applicable policies, procedures, controls, and standards required by the FDA Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the FDA Information Security Program security requirements, outlined in the FDA Information Security and Privacy Protection (IS2P) policy, by contacting the CO/COR or emailing your ISSO.

c. Privacy Act. Comply with the Privacy Act requirements (when applicable), and tailor FAR and HHSAR clauses as needed.

d. Privacy Compliance . Comply with the E-Government Act of 2002, NIST SP 800-53, and applicable FDA privacy policies and complete all the requirements below:

i. Per the Office of Management and Budget (OMB) Circular A-130, Personally Identifiable Information (PII), is "information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.

ii. Based on information provided by the ISSO, System/Data Owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

☐ No PII x PII

iii. The Contractor must support the agency with conducting a Privacy Threshold Analysis (PTA) for the information system and/or information handled under this contract to determine whether or not a full Privacy Impact Assessment (PIA) needs to be completed.

1. If the results of the PTA show that a full PIA is needed, the Contractor must support the agency with completing a PIA for the system or information after completion of the PTA and in accordance with HHS and FDA policy and OMB M- 03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002. The PTA/PIA must be completed and approved prior to active use and/or collection or processing of PII and is a prerequisite to agency issuance of an authorization to operate (ATO).

2. The Contractor must support the agency in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

e. Controlled Unclassified Information (CUI). Executive Order 13556 defines CUI as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing

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of the information." 81 Fed. Reg. 63323. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be:

i. Marked appropriately;

ii. Disclosed to authorized personnel on a Need-To-Know basis;

iii. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Information Systems and Organizations applicable baseline if handled by a contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and

iv. Returned to FDA control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800- 88, Guidelines for Media Sanitization.

f. Protection of Sensitive Information. For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) must protect all government information that is or may be sensitive by securing it with a solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.

g. Government Furnished Equipment (GFE) for Foreign Travel. FDA personnel are prohibited from taking GFE when participating in personal, unofficial travel to foreign countries. FDA personnel are strictly prohibited from teleworking using GFE in foreign countries. FDA personnel must also request loaner GFE from the FDA Foreign Travel program for official travel to any foreign country. Please see the FDA IS2P, Appendix T Government Furnished Equipment for Foreign Travel.

h. Confidentiality and Nondisclosure of Information. Any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA must be used only for the purpose of carrying out the provisions of this contract and must not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and must ensure that all work performed by its employees and subcontractors must be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed must be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein. The confidentiality, integrity, and availability of such information must be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS and FDA sanction policies and/or governed by the following laws and regulations:

18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

i. Internet Protocol Version 6 (IPv6). All procurements using Internet Protocol must comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).

j. Information and Communications Technology (ICT). ICT products and services from prohibited entities/sources must not be used/acquired in compliance with Public Law 115-232, Section 889 Parts A and B, FAR 4.21, FAR 52.204.23, FAR 52.204.24, and FAR 52.204.25. The contractor (and/or any subcontractor) must notify the government if they identify prohibited ICT products and/or services are used during the contract performance.

k. Government Websites. All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS must enable HTTP Strict Transport Security (HSTS) to instruct

compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, HTTPS is not required, but it is highly recommended. Consult the HHS Policy for Internet and Email Security for additional information.

l. Contract Documentation. The Contractor must use provided templates, policies, forms, and other agency documents to comply with contract deliverables as appropriate.

m. Standard for Encryption. The Contractor (and/or any subcontractor) must:

i. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

ii. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with an encryption solution that is validated with current FIPS 140 validation certificates from the NIST CMVP.

iii. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and FDA-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

iv. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 validation certificates from the NIST CMVP. The Contractor must provide a written copy of the validation documentation to the COR.

v. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys http://csrc.nist.gov/publications/. Encryption keys must be provided to the COR upon request and at the conclusion of the contract.

n. Contractor Non-Disclosure Agreement (NDA). Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract must complete the FDA non-disclosure agreement (3398 Form)], as applicable. Contractors (and/or subcontractors) must submit a copy of each signed and witnessed NDA to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

2. Training Requirements

a. Mandatory Training for All Contractor Staff. All Contractor (and/or any subcontractor) employees assigned to work on this contract must complete the applicable FDA information security awareness, privacy, and records management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees must complete FDA information security awareness, privacy, and records management training at least annually, during the life of this contract. All provided training must be compliant with HHS training policies.

b. Role-based Training. All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS and FDA policy.

c. Training Records. The Contractor (and/or any subcontractor) must maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records must be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

3. Rules of Behavior

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a. The Contractor (and/or any subcontractor) must ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, HHS Rules of Behavior for Privileged Users, and FDA policies and standards.
b. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Agency data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual FDA Information Security Awareness Training. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

4. Incident Response

o. The Contractor (and/or any subcontractor) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/FDA CIOCC /Incident Response Team teams within 24 hours, whether the response is positive or negative.
p. FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. In accordance with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information (PII), an incident is "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies" and a privacy breach is "the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose." For additional information on the HHS breach response process, please see the FDA IS2P Appendix F: Incident Response and the HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)."
d. In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) must:
i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract, with encryption solution that is validated with current FIPS 140 validation certificates from the NIST CMVP.
ii. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so, instructed by the Contracting Officer or representative, the Contractor must send FDA approved notifications to affected individuals as directed by FDA's SOP.
iii. Report all suspected and confirmed information security and privacy incidents and breaches to the FDA CIOCC, COR, CO, FDA SOP (or his or her designee), and other stakeholders, including breaches involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable FDA and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contact information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor must:

- Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;

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- Not include any sensitive information in the subject or body of any reporting e- mail; and
- Encrypt sensitive information in attachments to email, media, etc.

iv. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information, and HHS and FDA breach response policies when handling PII breaches.

v. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation on demand.

5. Position Sensitivity Designations

a. All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

x Does not apply

☐ Tier 1 Low Risk, Non-Sensitive, including HSPD-12 Credentialing

☐ Tier 2 Moderate Risk Public Trust (MRPT)

☐ Tier 3 Non-Critical Sensitive, National Security, including SECRET & "L" access eligibility

☐ Tier 4 High Risk Public Trust (HRPT)

☐ Tier 5 Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility

6. Homeland Security Presidential Directive (HSPD)-12

a. The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; OMB M-19-17; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

7. Roster

a. The Contractor (and/or any subcontractor) must submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to the COR and/or CO per the COR or CO's direction. Any revisions to the roster as a result of staffing changes must be submitted within a timeline as directed by the COR and/or CO. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

i. If the employee is filling a new position, the Contractor must provide a position description and the Government will determine the appropriate suitability level.

8. Contract Initiation and Expiration

a. General Security Requirements. The Contractor (and/or any subcontractor) must comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the

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contractor must follow the FDA EPLC framework and methodology in accordance with the FDA EPLC Project documentation, located here:
http://sharepoint.fda.gov/orgs/DelMgmtSupport/IntakeProc/EPLCv2/SitePages/v2/EPLCHome.as px and in accordance with the HHS Contract Closeout Guide (2012).

b. System Documentation. Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

q. Sanitization of Government Files and Information. As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) must provide all required documentation in accordance with SMGs published by FDA's Office of Acquisitions and Grant Services (OAGS) to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

r. Notification. The Contractor (and/or any subcontractor) must notify the CO and/or COR and system ISSO as soon as it is known that a contract employee will stop working under this contract.

s. Contractor Responsibilities upon Physical Completion of the Contract. The contractor (and/or any subcontractors) must return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor must provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and FDA policies.

t. The Contractor (and/or any subcontractor) must perform and document the actions identified in the FDA eDepart system
http://inside.fda.gov:9003/EmployeeResources/NewEmployee/eDepartDepartureSystem/default.htm as soon as it is known that a contract an employee will terminate work under this contract. The Contractor (and/or any subcontractor) shall coordinate with the COR via email, copying the Contract Specialist, to ensure that the appropriate person performs and documents the actions identified in the FDA eDepart system. All documentation must be available to the CO and/or COR upon request.

9. Records Management and Retention

a. The Contractor (and/or any subcontractor) must maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS Policy for Records Management and HHS and FDA policies and must not dispose of any records unless authorized by HHSFDA.In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, he/she must document and report the incident in accordance with HHS and FDA policies.

b. High Value Asset (HVA). If a system is identified as HVA,24 the contractor must comply with the FDA IS2P Appendix AB: High Value Asset (HVA) Program, the HHS Policy for the High Value Asset (HVA) Program, and the DHS HVA Control Overlay25 in addition to the above requirements.

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