Intent to Award Sole Source Contract 9/14/2026

The Food and Drug Administration (FDA) intends to award a sole source contract to the Reagan-Udall Foundation for the FDA (RUF) to support execution of its congressionally mandated regulatory mission across **16 project areas** addressing high-priority regulatory science gaps and public health challenges. The work — spanning structured stakeholder engagement, independent scientific convening, and landscape research — is a prerequisite to FDA's ability to develop sound regulatory frameworks and fulfill statutory obligations.

Each project area targets a specific gap where FDA cannot act without the scientific foundation, stakeholder input, or evidence infrastructure this contract provides. The contract is framed as a high-value investment: the cost of inaction — measured in delayed regulatory frameworks, preventable harm, and eroded public trust — exceeds the cost of the engagement.

Justification:

The Reagan-Udall Foundation for the FDA (RUF) was established by Congress under Title VI of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85, and codified at 21 U.S.C. § 379dd, as an independent, private, non-profit corporation with a statutory mandate to advance FDA's mission. Federal law expressly authorizes FDA to award grants, contracts, MOUs, and cooperative agreements to RUF in support of that mission.

The Pathways for Regulatory Innovation and Strategic Modernization (PRISM) framework has served as the primary vehicle for FDA-RUF collaboration, through which RUF has demonstrated a proven capacity to recruit expert panels, facilitate public workshops and private roundtables, conduct landscape reviews and stakeholder interviews, and produce white papers and summary reports — engaging more than 170 stakeholders on individual food safety initiatives alone.

This is a **new requirement**. FDA has previously supported RUF activities through grants and cooperative agreements rather than contracts; there is no prior contract history for this requirement. This contract represents the first procurement vehicle used to engage RUF under the PRISM framework, covering 16 discrete project requirements spanning CDRH, CDER, OCS, OCAC, and HFP for the period of September 30, 2026 through September 29, 2027.

Response to Notice:

Be advised that the aforementioned information is anticipatory in nature and is not binding. This notice is not a request for competitive proposals; however, any firm believing that they can fulfill the requirement of providing these services may be considered by the Agency. Interested parties shall identify their interest and capabilities in response to this synopsis

within 5 calendar days of publication and must clearly demonstrate their ability to successfully fulfill all the above requirements. The Government reserves the right not to respond to any expressions of interest received.

Only written comments, questions, or concerns regarding this notice will be accepted. Please submit them via e-mail to Howard Yablon at howard.yablon@fda.hhs.gov within the timeframe specified in this special notice. The Government will not reimburse any submissions. All costs associated with submitting a response will be the sole responsibility of the submitting party. A determination by the Government not to compete this proposed contract action based upon responses to this notice will be made at the sole discretion of the Government.

The Government will review all submitted information solely to determine whether to pursue a competitive procurement process. If the Government decides to award the proposed sole source contract, the justification and approval documentation will be posted on this website.

All information received in response to this notice that is marked Proprietary will be handled accordingly. The Government shall not be liable for or suffer any consequential damages for any proprietary information not properly identified. Proprietary information will be safeguarded in accordance with the applicable Government regulations.

Submissions will not be returned.