**FDA-RFP-1226930**

**Statement of Work**

***\*Note that this sample has been revised from the source document on the Government Point of Entry as necessary to align formatting and applicable FAR procedures.\****

# Part 1 – Description

The U.S. Food and Drug Administration’s (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Nutrition and Food Labeling requires a contract to conduct a market research study on the cell cultured food industry. This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in Federal Acquisition Regulation (FAR) Part 12.603. This announcement constitutes the only solicitation; proposals are being requested, and a separate written solicitation will not be issued.

This solicitation is a Request for Proposal (RFP) using FAR Parts 8 procedures. The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2020-07 dated July 2, 2020. The North American Industry Classification System (NAICS) code for the proposed acquisition is 541910, Market Research and Public Opinion Polling, Small Size Standard $15,000,000.00. This requirement set-aside for small businesses only under multiple award schedule category Market Research and Public Opinion Polling.

This requirement is to conduct market research on the current landscape of the cell cultured food industry to gain an understanding of the potential market, including timing, types of products, labeling, and related foods to inform policy decisions regarding the modernization of standards of identity and related issues for labeling these foods produced using cell culture and related technology.

# Part 2 – Supplies or Services and Prices

Purchase Order Type: Firm-Fixed Price

**2.1 Pricing Schedule**

|  |  |  |
| --- | --- | --- |
| **CLIN** | **Deliverable** | **Price** |
| 0001. | Kickoff Meeting |  |
| Initial Project Plan |  |
| Bi-Monthly Progress Report |  |
|  | Collection and Analysis of Data |  |
| Preliminary Results |  |
| Draft Report |  |
| Final Report |  |
|  | **Total Price** |  |

## Payment is only authorized for the respective firm-fixed-price upon successful completion of the respective CLINs, including delivery and acceptance of all deliverables, as determined by the FDA Contracting Officer’s Representative (COR) according to the Statement of Work, and upon submission of a proper invoice. Proper invoice submission includes following the invoice instructions below. The amount invoiced shall be derivative of the number of ownership verifications performed for that billing period at the approved per unit rate.

**Part 3 – Description/Specifications**

* 1. **Background**

Section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishes the legal authority for the FDA to promulgate standards of identity for food. Under section 401 of the FD&C Act (U.S.C. 341) the Secretary, can establish for any food, under its common or usual name, a reasonable definition and standard of identity, reasonable standard of quality, or reasonable standards of fill of container, if such action will promote honesty and fair dealing in the interest of consumers.

FDA began establishing Standards of Identity (SOI) shortly after the Federal Food, Drug, and Cosmetic (FD&C) Act was enacted in 1938 to “promote honesty and fair dealing in the interest of consumers” and, since this time, has established more than 280 SOI for a wide variety of food products. SOI typically set forth permitted ingredients, both mandatory and optional, and sometimes describe the amount or proportion of each ingredient. Many SOI also prescribe a method of production or formulation. A food is misbranded if it purports to be or is represented as a food for which a SOI has been established but fails to conform to the standard. As a large percentage of SOI were issued decades ago, various stakeholders have expressed concerns that many SOI are out-of-date and may impede innovation – including the ability to produce healthier foods.

On March 29, 2018, FDA Commissioner Dr. Scott Gottlieb, M.D. announced a comprehensive, multi-year FDA Nutrition Innovation Strategy (hereinafter the “NIS”). The NIS focuses, among other things, on providing incentives for food manufacturers to produce products that have more healthful attributes. Under the NIS, FDA is seeking to modernize food Standards of Identity (SOI) in a manner that will achieve three primary goals: (1) protect consumers against economic adulteration; (2) maintain the basic nature, essential characteristics, and positive nutritional attributes of food; and (3) promote industry innovation and provide flexibility to encourage manufacturers to produce more healthful foods. To inform this effort, FDA is seeking information to learn what changes have occurred in food production, manufacturing, and marketing that FDA should be aware of when reviewing its SOI regulations and related labeling regulations and exploring how to modernize. FDA is also seeking information regarding consumer demographics and expectations.

These tasks will support and inform FDA policy decision regarding the modernization of standards of identity and related issues of product labeling for these product categories.

## Objective

The primary objective of this task is to conduct a study of the current landscape of the cell cultured food industry to gain an understanding of the potential market, including timing, types of products, labeling, and related foods. Note that the term “animal” refers to meat, poultry, and seafood.

The study may be used to inform future CFSAN policy.

## Statement of Work

The Government requires general economic consulting and project management services familiar with experience conducting expert elicitations. Independently and not as an agent of the Government, the Contractor shall furnish the necessary materials, services, facilities, and otherwise do all things necessary for or incident to the performance of the work set forth herein.

* + 1. **Specific Tasks**

The Contractor shall furnish the necessary personnel, services, and facilities to collect and conduct an analysis of data relating to the juice and beverage industry and olive oil industry. The Contractor shall help develop the study and analysis design that will best achieve the study objectives, summarize the results, and submit draft deliverables at the schedule shown below for both industries**.** The study design and all deliverables will all be reviewed by the government Project Advisory Group (PAG) for approval before the Contractor begins the next stage of work.

**Project Planning**

The Contractor shall arrange a kick-off meeting with the Contractor’s team within thirty (30) days of award to achieve a clear and mutual understanding of all contractual requirements. Discussion will include a description of the information to be included in the project, concept requirements, and an estimated timeframe for each phase of the study for each industry. All project requirements and expected deliverables for both industries must be discussed and agreed upon before moving to the next phase.

To ensure the project is well thought out in sufficient detail, the Contractor shall work with the FDA staff to develop the project approach for each industry in detail. The Contractor shall provide a written project plan for each industry outlining, timelines, and the deliverables.

The project plans for each industry should outline the overall project with government input and approval.

The Contractor shall complete all tasks necessary to successfully coordinate, document and prepare detailed written summary statements of meeting and data analysis results for each task.

The Contractor shall coordinate and prepare correspondence articulately for a broad audience of FDA stakeholders, which requires minimal rework after being presented to the Contracting Officer Representative (COR) for execution.

The Contractor, in coordination with the Government, shall identify and finalize the list of possible data sources for each task to analyze based on the objectives of the study. Depending on the data identified as necessary, the Government may share data it owns.

The Contractor shall produce well written, concise, detail summary documents resulting from organizational meetings and forums.

**Project Development**

The Contractor shall work with the FDA PAG to develop a study to analyze the following characteristics of foods produced using cell culture and related technology:

1. What companies are developing cell culture technologies.
2. Which specific animal species are currently in development to have cell cultured alternatives.
3. The physical forms of food that is anticipated to come into the marketplace.
4. Terms which might be used to describe the physical forms (for example, burgers, chunks, fillets, etc.)
5. Potential claims on products which are derived from cell cultured production.
6. Estimates of when food products produced using cell culture technology will come to market.
7. The number and type of products currently on the market which contain animal products which have been traditionally produced and plant-based proteins combined into one food.
8. The types of proteins which are being used in combination with traditional animal products in these foods.
9. The statements of identity and claims being used on these combined plant and animal foods.
10. The international regulatory landscape for foods produced using cell culture technology.
11. When foods produced from cell culture technology could first appear on the international market.
12. The availability and/or development of other foods produced using technologies similar to cell culture technology, but which do not use the cells of whole animals (for example, milk or egg proteins produced using yeast or bacterial cultures).

Note: Suggested content areas are subject to change/addition dependent on Task 1.

The Contractor shall provide analysis plan outline of research reports and FDA will review and provide approval within set timeframe as requested.

**Execute the Study**

The Contractor shall collect the relevant data and perform a detailed review of data; analyze gaps and constraints of the data; clean and analyze the data to provide analysis of the characteristics (discussed in Task 2) of the cell culture technology. Depending on the data identified as necessary, the FDA may share data it owns.

The FDA shall coordinate a bi-monthly (or more frequent as needed) conference call to review the activities during each month, and activities planned for the ensuing month. If needed the FDA representative(s), along with the Contractor shall coordinate in person meetings to ensure that the task is progressing in a timely manner.

Deliverable: The Contractor shall collect and compile the content of the analysis meeting all requirements of the statement of work, contract, and ensure all responses are well documented. Contractor will review, analyze, and evaluate data, and prepare a draft report describing the findings, results and recommendations from this activity, to assist, improve, and otherwise enhance an understanding of the foods produced using cell culture and related technology. Collection and analysis of data should be completed within 90 days after the kick-off meeting. The draft report with the related justifications shall be submitted within 30 days after the submission of the preliminary results.

**Summarize Findings**

The contractor shall provide a summary report to the FDA, along with an executive summary describing the main points, findings, and other significant information that will need immediate internal review and deliberation.

This final report shall provide relevant statistics and visual relationships- utilizing tables, graphs, charts, other visual descriptors, to illustrate the findings of the analysis as necessary. Similarly, the final report summary shall provide an explanation as to the potential impact any gaps or constraints in the data may have representative to the nature of the analysis as applied to the foods produced using cell culture and related technology.

Deliverable: The final report shall include a summation of the work performed and shall be in sufficient detail to describe comprehensively the results achieved for the entire contract period of performance. The final report shall include all deliverables that will fully document the final report and project outcomes, finding and results. The final report should be submitted not later than 21 calendar days prior to the last day of this contract period of performance.

# Part 4 –Performance and Deliverables

## Deliverable Table

The contractor is responsible to provide all the services specified above and shall adhere to the following performance requirements.

|  |  |  |  |
| --- | --- | --- | --- |
| **Format** | **Format** | **Due Date** | **Recipient** |
| Kick-off Meeting | In Person | 30 days after award date. | COR/PO |
| Initial Project Plan | Microsoft | 3 weeks after kick-off meeting. | COR/PO |
| Bi-Monthly Progress Report | Microsoft | Every two Months | COR/PO |
| Collection and analysis of data | Microsoft | 90 days after kick-off meeting | COR/PO |
| Preliminary Results | Microsoft | 30 days after data analysis. | COR/PO |
| Draft Report | Microsoft | 30 days after the preliminary results. | COR/PO |
| Final Report | Microsoft | Not later than 21 calendar days prior to the last day of this contract period of performance. | COR/PO |

## Place of Performance and Work Hours

The majority of the work shall be performed at the contractor’s site.

## Inspection and Acceptance

The Contracting Officer’s Representative will perform inspection of the services to be provided. The Contracting Officer’s Representative – to be determined upon contract award - is the authorized representative of the Contracting Officer.

The COR will review and communicate acceptance or rejection of deliverables to the Contractor no later than ten (10) business days prior to the end of the month. The contractor will have five (5) business days to correct and resubmit the rejected deliverables.

## 4.4. Conflict of Interest

The Contractor shall warrant that, to the best of its knowledge and belief, and except as otherwise disclosed in its proposal, it does not have any actual, potential, or apparent conflict of interests pertaining to the subject procurement, as described in FAR Subpart 9.5 and U.S. Health and Human Services (HHS) and FDA policies, for its organization, employees, or subcontractors proposed to be working under the procurement.

After award of an order for this procurement, if the Contractor discovers an actual, potential, or apparent conflict of interest with respect to this procurement, it shall make an immediate and full disclosure in writing to the FDA Contracting Officer and COR for this order, including a description of any actions the Contractor has taken or proposes to take to avoid, neutralize, or mitigate any conflict of interest. The Contractor shall act impartially and objectively and must avoid actions that would cause a reasonable person to question their impartiality or engage in activities that may result in an unfair competitive advantage.

The Government reserves the right to exercise any remedy available at law or equity, including termination of the order for cause or convenience, should the Government determine remedial action is necessary to address any actual, potential, or apparent conflict of interest.

The Contractor shall include a clause substantially similar to this “Conflicts of Interest” clause in any subcontract.

## Period of Performance

The period of performance for this contract is for one year (1) from date of award.

## Government Furnished Equipment Property (GFE/GFP)

Government Furnished Equipment. If necessary, the government shall provide the workspace, telecommunication, data communications, and network security facilities needed to support the tasks and assignments of this contract. The government also will supply email and Internet access capability if necessary.

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