

Request for Proposals RFP No: 25-05-2022

Vitamin A Soft Gelatin Capsules 2023 Procurement

Issued by Nutrition International

Deadline for receipt of proposals at Nutrition International:

Thursday, June 9th, 2022 16:00 Eastern Standard Time

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1.0 REQUEST FOR PROPOSALS

- 1.1 This Request for Proposals ("RFP") is an invitation by Nutrition International ("NI") to prospective Contractors to submit proposals for the sale of Vitamin A Soft Gelatin Capsules that are to be delivered to the UNICEF warehouse in Copenhagen, Denmark or other destinations as requested by NI. The supply is intended for distribution to developing countries.
- 1.2 All enquiries pertaining to this RFP must be sent in writing by email to proposals@nutritionintl.org with the subject line including the words "RFP No. 25-05-2022", before 16:00 EST on Thursday June 2, 2022. Questions received thereafter will not be answered. Substantive enquiries (without attribution of the source) and responses to them shall be shared with all parties and shall form part of this RFP. Responses will be sent as soon as possible. Should questions not be answered, Contractors should submit their proposals prior to RFP closing just the same.
- 1.3 Proposals must be sent electronically (via email to proposals@nutritionintl.org) by *no later than 16:00 EST (Ottawa) on Thursday June 9 2022*.

2.0 ELIGIBILITY OF CONTRACTORS

- 2.1 This RFP is open only to Contractors who have received notification from NI that they have been pregualified to sell product(s) stated in their response to NI's Expression of Interest No. 04-03-2022.
- 2.2 The products which the Contractor proposes to supply must be only those proposed by the Contractor in Expression of Interest No. 04-03-2022 and for which NI provided written confirmation of prequalification.
- 2.3 Contractors will be required to demonstrate to NI that they are able to meet all the requirements of this RFP; are technically, managerially and financially able to perform and complete any resulting Contract; and will be production-ready at the time of expected award of Contract. These factors will be considered in the evaluation.
- 2.4 Contractors must disclose in their proposal details any circumstances, including personal, financial and business activities that will, or might, give rise to a conflict of interest. This disclosure must extend to all personnel proposed to undertake the work should a contract be awarded.
- 2.5 Where Contractors identify any potential conflicts, they must state how they intend to avoid any impact arising from such conflicts. NI reserves the right to reject any proposals which, in NI's opinion, give rise, or could potentially give rise to, a conflict of interest.
- 2.6 Contractors must also disclose:
 - 2.6.1 If they are or have been the subject of any proceedings or other arrangements relating to bankruptcy, insolvency or the financial standing of the Contractor including, but not limited to, the appointment of any officer, such as, a receiver in relation to the Contractor's personal or business matters or an arrangement with creditors or of any other similar proceedings.
 - 2.6.2 If the company or key management have been convicted of, or are the subject of any proceedings, relating to:
 - a criminal offence or other offence, a serious offence involving the activities of a criminal organization or found by any regulator or professional body to have committed professional misconduct

- II. corruption including the offer or receipt of any inducement of any kind in relation to obtaining any contract, with NI, or any other contracting body or authority
- III. failure to fulfil any obligations in any jurisdiction relating to the payment of taxes

3.0 GENERAL CONSIDERATIONS

- 3.1 Contractors are responsible for all costs associated with proposal preparation and submission.
- 3.2 Proposals shall remain irrevocable in the form submitted by a Contractor for a period of 180 days after the deadline for submission of proposals.
- 3.3 If NI selects a Contractor(s) to supply vitamin A Soft Gelatin Capsules to NI, the selected Contractor(s) will be notified by NI and must enter into an agreement in the form of the contract attached as Annex Sample Contract to this RFP (the "Contract"). In the event of a Contract award, all the terms and conditions of this RFP and its Annexes, including the Contractor's response to the RFP, will form part of the Contract, unless otherwise negotiated.

A selected Contractor(s) who enters into a Contract with NI is referred to in this Request for Proposals as a "Contractor".

4.0 SCOPE OF PROPOSAL

- 4.1 **SUPPLY REQUIRED:** Bottled soft gelatin capsules containing Vitamin A meeting the specifications for the product, packing, bottling, labelling and all other requirements detailed in <u>Annexes B</u> & <u>D</u> as follows:
 - 4.1.1 Refer to Annex B for Vitamin A Soft Gelatin Capsules Technical Product Specifications.

Refer to Annex D for the following:

- 4.1.2 Desiccant Pack Specifications.
- 4.1.3 Specifications for Packing; Pallets and Boxes; Pallet and Box Labels.bb
- 4.1.4 Bottle and Bottle Label Specifications.
- 4.2 All references to Vitamin A capsules in all documents of the proposal should use NI's product item classification system below.
 - 4.2.1 **Item 1:** 200,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, **500** capsules per bottle, Desired Shelf-Life: 36 months
 - 4.2.2 **Item 2:** 200,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, **100** capsules per bottle; Desired Shelf-Life: 36 months
 - 4.2.3 **Item 3:** 100,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, **500** capsules per bottle; Desired Shelf-Life: 36 months
 - 4.2.4 **Item 4:** 100,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, **100** capsules per bottle; Desired Shelf-Life: 36 months

4.3 **QUANTITIES REQUIRED:** The total number of Vitamin A Soft Gelatin Capsules required is estimated to be **up to 448,420,758** packaged in bottles of 500 capsules **or** packaged in bottles of 100 capsules.

Contractors will be asked to propose prices for the quantities required of each product Item which NI approved at the time of pre-qualification as shown below:

Capsule Type	Bottle count size (Number of capsules/ bottle)	Number of bottles	Total Number of capsules
Item 1 200,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules	500	Up to 730,029	Up to 365,014,349
Item 4 100,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules	100	Up to 834,064	Up to 83,406,409

- 4.4 **COMPLIANCE WITH GOOD MANUFACTURING PRACTICE:** Vitamin A Soft Gelatin Capsules at these high doses are to be considered pharmaceutical products and must be manufactured in accordance with prevailing Good Manufacturing Practices (GMP) Standards for pharmaceutical products as verified by the relevant National Drug Regulatory Authority, and by one or more internationally recognized authorities (that are members or partners of the Pharmaceutical Inspection Cooperation Scheme [PIC/S].
- It will be a condition for receiving a contract from NI that a Contractor demonstrates adherence to Good Manufacturing Practices meeting pharmaceutical Standards to NI and UNICEF. Selected Contractors will be asked to make available their facilities, on short notice, so that NI and/or UNICEF or their designated representatives may carry out a site inspection and quality assessment at any time prior to or while the Contract is in force.
- 4.6 **REQUIRED DELIVERY SCHEDULE:** The target arrival date for the first shipments of capsules at the Delivered at Place (DAP) point is no later than **30 November 2022**. It is expected that all deliveries will be completed by **31 January 2023**. **Contractors should also propose shipments that are most efficient and cost effective for NI**.

4.7 **DELIVERY DETAILS:**

Contractors should note that:

- 4.7.1 The delivery date at the DAP point is to be understood as the date the goods arrive at DAP point (final destination). The DAP point is UNICEF Supply Division Warehouse, Skagerrakvej 6, 2100 Copenhagen, Denmark.
- 4.7.2 Only goods meeting the technical product specifications in Annex B: Vitamin A Soft Gelatin Capsules Technical Product Specifications are to be shipped from the Contractor.
- 4.7.3 At the time of shipment from the Contractor, 36-month shelf life products must be no more than four (4) months old from the date of manufacture.
- 4.7.4 Any and all shipments must be made by full container loads only. Any lesser quantity, such as half container loads, is not acceptable, unless otherwise authorized by NI.
- 4.7.5 No goods in quarantine are to be shipped.

- 4.7.6 Exceptionally, some deliveries may be required to be made directly to UNICEF Field Offices in developing countries around the world. In all cases the clauses below on Freight, Freight Insurance and Product Liability will apply.
- 4.7.7 For shipments arriving via sea, NI/UNICEF will need to be notified on the number of free days that has been negotiated at the Copenhagen port with the Contractor's freight forwarder. The required number of days is not contract bound, but it would be ideal to have 7 free (work) days if possible.
- 4.8 **FREIGHT INSURANCE AND PRODUCT LIABILITY INSURANCE:** The Contractor will pay freight as per the DAP terms (Incoterms 2010) as specified in 4.7. NI will reimburse the actual cost thereof in accordance with the Contract.
- 4.9 The Contractor will be required to arrange and pay for freight insurance at 110% of the value of the shipment. NI will reimburse the actual cost thereof in accordance with the Contract.
- 4.10 **PRODUCT LIABILITY INSURANCE:** The Contractor shall carry Product Liability Insurance in an amount of no less than CAD \$6,000,000 with respect to the Contract. The Contractor warrants that it will include NI as additional insured for the Contract and for its duration including the warranty period (see 7.1).
- 4.11 Such insurance may be renewed but cannot be changed or cancelled without the prior written approval of NI. The Contractor will be required to provide a copy of the insurance policy each year until the end of the warranty period on the expiration date of the policy.

5.0 INSTRUCTIONS FOR SUBMISSION OF PROPOSALS

- 5.1 Cover letter
 - 5.1.1 Contractors <u>are required</u> to submit a cover letter expressing interest in participating in the RFP, confirming that all information submitted is true and correct, and confirming that the manufacturing facility has the capacity to produce Vitamin A in accordance with the technical requirements for the product as set out in this RFP and the delivery schedule and pricing table provided in their proposal.
 - 5.1.2 Contractors <u>are required</u> to complete a Risk Assessment Register as set out in (Annex J).
 - 5.1.3 New Contractors are requested to complete the New Supplier References as set out in (Annex K).
- 5.2 Pricing table
 - 5.2.1 The Pricing Table (Annex H) must be completed and submitted as part of the proposal.
 - 5.2.2 Contractors must provide cost per bottle for capsules in CAD.
 - 5.2.3 All prices provided in the Pricing Table shall be firm and fixed until completion of the award period.
 - 5.2.4 Prices for capsules must be provided separately in the Pricing Table. All manufacturing-related expenses and charges must be included within the unit price for capsules, including but not limited to production, quality assurance, packaging (including labels), packing suitable for export and in accordance with terms and conditions as set out by this RFP, and preservation in accordance with standard commercial practices unless otherwise specified.
 - 5.2.5 Prices for Freight must be provided separately in the Pricing Table. Shipping terms used must be in accordance with the International Chamber of Commerce Incoterms

- 2010. Freight prices must be quoted on the basis of:
- 5.2.6 Delivered at Place (DAP) UNICEF Supply Division Warehouse, Skagerakvej 6, 2100 Copenhagen, Denmark
- 5.2.7 Prices for Insurance must be provided separately in the Pricing Table. Freight insurance must be 110% of the value of the shipment.

5.3 Discounts

- 5.3.1 Contractors are requested to advise as to quantity/volume discounts in the form of large quantity/volume discounts and staircase pricing (i.e. varying prices according to different quantities procured).
- 5.3.2 Should the Contractors determine that a number of bottles other than the ranges specified in the Pricing Table (Annex H) result in a preferable pricing scheme, Contractors are encouraged to submit a second, additional table specifying these alternative ranges.

5.4 Lead time

- 5.4.1 Contractors are required to indicate the realistic lead time for delivery of each product in the Lead Timetable (Annex H).
- 5.4.2 Delivery lead time is the period from the date of receipt of a purchase order by the Contractors to the date of delivery of the goods to the Delivered at Place (DAP) point in accordance with the applicable delivery terms and instructions specified. The lead time includes the period for manufacturing and packing the products, pre-delivery inspection (if applicable), obtaining any necessary regulatory authority approvals or licenses, shipping, and provision of all documentation required in connection with such delivery.
- 5.4.3 The DAP point is UNICEF Supply Division Warehouse, Skagerakvej 6, 2100 Copenhagen, Denmark.

5.5 Delivery schedule

- 5.5.1 The Delivery Schedule (Annex I) must be completed and submitted as part of the proposal.
- 5.5.2 All delivery dates shall be firm and fixed until completion of the period of award and will remain firm for any amendment of the award.
- 5.5.3 The delivery date at the Delivered at Place (DAP) is the date the goods arrive at DAP point (final destination). The DAP point is: UNICEF Supply Division Warehouse, Skagerakvej 6, 2100 Copenhagen, Denmark.
- 5.5.4 Only goods meeting the technical specifications set out in this RFP are to be shipped.
- 5.5.5 At the time of shipment from the Contractors, products with a shelf life of 36 months must be no more than four months from the date of manufacture. No goods in quarantine are to be shipped.

5.6 Audited financial statements

5.6.1 Contractors <u>must submit</u> their most recent audited financial statements in support of their proposals.

6.0 REQUIREMENTS

I. LETTER OF CONTRACTOR CERTIFICATION

A signed original letter as per **Annex A** is required.

II. TABLE OF INGREDIENTS, MATERIALS AND SUPPLIERS

Any product offered must meet the product specification as detailed in <u>Annex B</u> & <u>Annex C</u>. Conformity to this requirement may be verified by inspection, as referred to in paragraphs 4.4 and 4.5.

Contractors are required to fill out the Table of Ingredients, Materials and Suppliers in Annex G, listing all the ingredients and excipients used to make up the Vitamin A Soft Gelatin Capsules and the primary and secondary packaging to be used.

Contractors are required to disclose the names and addresses of intended material suppliers, and for ensuring that Contractor(s) of all excipients used conform to all requirements stated in this RFP, and are identical to the Contractors listed in their response to NI's Expression of Interest No. 04-03-2022.

III. PRICING TABLE

The Pricing Table in Annex H must be completed and submitted as part of the proposal. All prices shall be firm and fixed until completion of contract and will remain firm for any amendment of contract.

Contractors must quote unit prices for pre-qualified product(s), where applicable using bottles of 100 and 500 capsules as the units of measure, net of freight and insurance costs. Product prices must cover all expenses and charges of whatever nature including but not limited to production, quality assurance, packaging (including labels), packing suitable for export and in accordance with terms and conditions as set out in this RFP, and preservation in accordance with standard commercial practices, unless otherwise specified.

Contractors must quote freight and insurance separately in the Pricing Table in <u>Annex H</u> Contractors must quote freight prices on the basis of DAP UNICEF Warehouse, Copenhagen. The shipping terms used must be in accordance with the International Chamber of Commerce Incoterms 2010.

Contractors should note that under the Convention on the Privileges and Immunities of the United Nations, UNICEF, as a subsidiary organ of the UN, is exempt from direct taxes and customs duties in respect of articles exported or imported for its official use. In the event any governmental authority refuses to recognize these exemptions, the Contractor shall notify NI immediately who will consult with UNICEF to determine an acceptable procedure.

Contractors must quote all prices in Canadian Dollars (CAD), exclusive of Goods and Services Tax (GST), Harmonized Sales Tax (HST), Value Added Tax or refundable Excise Taxes or customs duties paid on imported materials, parts and components incorporated or to be incorporated in the supplies.

IV. DELIVERY SCHEDULE

Contractors must provide their best delivery schedule and indicate the validity period of the proposed delivery schedule based on the DAP point using the delivery schedule format in <u>Annex I</u>. Delivery schedules will be evaluated against the delivery date at the DAP point. The target arrival date for the first shipments of capsules at the DAP point is no later than **30 November 2022**.

It is expected that all deliveries will be completed by 31 January 2023.

Where possible, Contractors should limit each shipment to five containers per shipment.

Should a lesser quantity of product be awarded in the Contract, the Contractor will adhere to the delivery schedule submitted in its proposal **until the total quantity of product ordered has been shipped**. Failure to respect the delivery schedule could result in cancellation of the Contract at no cost to NI.

V. HALAL CERTIFICATION

Contractors must provide a valid Certificate of Registration from an internationally recognized certifying agency, such as the Islamic Food and Nutrition Council of America (IFANCA) as proof that all facilities involved in the manufacture of the finished product have been approved to meet Islamic Halal requirements.

This requirement also applies to all excipient Contractors supplying materials for the finished product.

VI. AUDITED FINANCIAL STATEMENTS

Contractors must submit their most recent audited financial statements in support of their proposals.

7.0 WARRANTY AND WARRANTY PERIOD

- 7.1 Contractors are made aware that a successful Contractor will be required to warrant the quality of the Goods and their expiry date (at minimum 24 months from the date of original manufacture) and that the Goods will be free from defects in material workmanship. The product shall conform to the specifications provided in <u>Annex B</u>;
- 7.2 The Goods shall be fit for the purposes for which such goods are ordinarily used or purposes expressly made known to the Contractor by NI. All defective Goods identified before the expiry date that can be attributed to the original manufacturing process as a result of a joint investigation will be replaced by the Contractor at no cost to NI, or an amount equivalent to re-procurement costs will be paid by the Contractor, whichever is most advantageous to NI.

8.0 SOURCE OF FUNDS

8.1 Procurement of the Vitamin A Soft Gelatin Capsules is subject to the availability of funds from NI's third party donor.

9.0 EVALUATION AND SELECTION PROCESS

- 9.1 The objective of the Evaluation Process is to identify the Proposal that effectively meets the requirements of this RFP and provides the best value. All determinations are made at the sole discretion of NI.
- 9.2 Review of Mandatory Requirements Each proposal first will be evaluated for completeness of the submission. Failure to comply with any of the terms and conditions contained in the RFP including, but not limited to, failure to provide all the required information or documentation, may result in disqualification.
- 9.3 Commercial Offers will be evaluated based on their compliance with the requirements as set out in Section 5 of this RFP. Evaluation considerations include but are not limited to:
 - competitiveness of pricing.
 - · compatibility of delivery schedule with needs.
 - prior performance (for previously contracted Contractors):
 - · risk assessment and identification; and

- managerial and financial ability to complete the tasks set out in the RFP.
- 9.4 Contractors may be requested to correct errors or inconsistencies identified by NI during the proposal evaluation process. Contractors that do not comply with such requests within the timeframe communicated will be disqualified.
- 9.5 As needed, each Contractor will permit NI and UNICEF, either themselves or through a designated representative entity, to have access to the facilities where the products are manufactured, at all reasonable times to inspect the manufacturing site and processes for the production, quality control, quality assurance, and packing of the products. The Contractor will provide reasonable assistance to the representatives for such appraisal, including copies of any documentation (including, but not limited to, test results or quality control reports) as may be necessary, at its own cost. The inspection may be carried out in conjunction with the appropriate national authority. Failure to do so may result in the rejection of the proposal.
- 9.6 All the terms and conditions of this RFP and its Annexes, including the Contractor's response to this RFP will form a part of the award unless otherwise negotiated. The Contractor understands that if it proposes an amendment or additional terms to the award, these must be clearly detailed in the proposal and may affect the evaluation of the proposal.

9.7 NI reserves the right to:

- a. At any time prior to submission deadline, and for any reason, amend the RFP document. All Contractors that have confirmed their intent to submit will receive notification of the amendment, and it will be posted on the NI website.
- b. Disqualify any or all Contractor(s) without incurring any liability to the affected Contractor(s).
- c. Negotiate with one or more technically compliant suppliers and seek a best and final offer (BAFO) on any part of the technical or price/cost proposals submitted, as part of this RFP process.
- d. Accept other than the lowest price proposal.
- e. Reject any proposals which, in their opinion, give rise, or could potentially give rise to, a conflict of interest.
- f. Accept any proposal, in whole or in part; to reject any or all proposals; or to cancel this solicitation process in its entirety.
- g. Verify any information contained in the Contractor's response. The Contractor will provide reasonable cooperation with such verification.
- h. Invalidate any proposal received from a Contractor that, in the sole opinion of NI, has previously failed to perform satisfactorily or complete contracts or purchase orders on time, or that NI believes is not able to meet the requirements of the RFP.
- Invalidate any proposal that, in the sole opinion of NI fails to meet the requirements and instructions stated in this RFP.
- j. Suspend negotiations or withdraw an award to a Contractor at any time. NI is not required to provide any justification but will give notice prior to any such suspension of negotiations or withdrawal of award.

10.0 NOTIFICATION OF AWARD

In the event of a delay in the Contract award, and prior to the expiration of the 180-day period referred to in Section 3.2, NI will notify the successful Contractor(s) in writing and a Contract will be issued shortly thereafter subject to the considerations listed in 9.7.

11.0 LIST OF ANNEXES

Reference Documents:

Annex A: Letter of Manufacturer Certification

Annex B: Product Technical Specifications

Annex C: Minimum Information Requirements for Stability Testing Protocols and Report

Annex D: Technical Specifications for Packaging

Annex E: NI Sample Contract for Commodities

Annex F: Further References

Required for Completion by all Contractors:

Annex G: Table of Ingredients, Materials, and Suppliers

Annex H: Pricing Table

Annex I: Delivery Schedule

Annex J: Risk Assessment Register

Annex K: New Supplier References

12.0 KEY DATES & DELIVERABLES

Activity	Dates
RFP Issued	May 26, 2022
Confirmation by Contractors on Intent to Bid (via email) proposals@nutritionintl.org	June 1, 2022
Inquiries & Questions from Contractors (via email) proposals@nutritionintl.org	June 2, 2022
Deadline for Receipt of complete commercial offers	June 9, 2022
Notification by NI on outcome of the evaluation process (via email) proposals@nutritionintl.org	June 24, 2022