NUTRITION INTERNATIONAL

Nourish Life

Request for Proposals
RFP No: 12-01-0018
Vitamin A Soft Gelatin Capsules

Issued by Nutrition International

Date of Issue: May 24, 2019

Deadline for receipt of proposals:
DATE: June 21, 2019
TIME: 23:59 Ottawa EST (Eastern Standard Time)

Contents

1. Purpose of the Solicitation

1.1 Background

1.1.1 Nutrition International (NI) is an international not-for-profit organization dedicated to transforming the lives of vulnerable people, especially women, adolescent girls, and children, by improving their nutritional status.

1.1.2 NI works in partnership with UNICEF to implement the Vitamin A Contribution-in-Kind (CIK) Program, which provides donations of Vitamin A soft gelatin capsules to approximately 60 countries around the world. These capsules are used by national governments to support supplementation programs targeting children aged 6-59 months of age.

1.1.3 Within the Vitamin A CIK Program, NI is responsible for procuring Vitamin A soft gelatin capsules. To this end, since 1998 NI has procured approximately 500 million Vitamin A soft gelatin capsules per year.

1.1.4 This Request for Proposals (RFP) represents a joint technical collaboration between NI and UNICEF for the purposes of pre-qualifying interested proponents for the supply of Vitamin A soft gelatin capsules, in accordance with the directives set out herein. Any commercial offer and evaluation process involving pre-qualified proponents for UNICEF, will be conducted at a later date, as determined by UNICEF.

1.1.5 Objectives of the solicitation are to expand the supplier base, increase competition, and ensure timely delivery and best value for money for Vitamin A supplementation programmes supported by NI and UNICEF.

2. Technical Specifications (NI & UNICEF)

2.1 Product technical specifications

2.1.1 The product technical specifications form Annex B of this document.

2.1.2 Adherence to specifications is a requirement. However, NI/UNICEF reserve the right to amend/revise the specification as deemed necessary.

2.2 Stability Requirements

2.2.1 NI/UNICEF may decide to award conditional to proponents based on review of e.g. ongoing stability data and commitment to continue long-term testing over the shelf life period. The specifications for the stability requirements for Vitamin A soft gelatin capsules are contained within Annex B of this document.

2.3 Packaging

2.3.1 All the technical packaging requirements and specifications for primary and secondary packaging; and desiccants are listed in Annex D.

3. General Submission Requirements (NI & UNICEF)

3.1 Preparation of proposals

3.1.1 In response to this RFP, proponents will prepare proposals composed of two offers: a) a Technical Offer in accordance with the requirements as stated in Section 4 of this RFP; a Commercial Offer, in accordance with the requirements as stated in Section 5 of this RFP.

3.1.2 All proposals and required documentation must be provided in English.

3.1.3 Proponents must indicate the validity period of their proposals. Proposal must be valid at least 180 days from the submission deadline.
3.1.4 Proponents are responsible for all costs associated with proposal preparation and submission.
3.1.5 Proponents must respond to all the requirements stated in this RFP for Items 1-4.
3.1.6 Where any certifications submitted as part of this RFP expire before or during the period of the award, the proponent will be required to submit renewed certificates. Any costs associated with this will be borne by the proponent.
3.1.7 Proponents must disclose 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 the proponent receive an award. Where proponents identify any potential conflicts, they must state how they intend to avoid any impact arising from such conflicts.
3.1.8 Proponents must disclose if they are or have been the subject of any proceedings or other arrangements relating to bankruptcy, insolvency, or the financial standing of the proponent including, but not limited to, the appointment of any officer such as a receiver in relation to the proponent's personal or business matters or an arrangement with creditors or of any other similar proceedings.
3.1.9 Proponents must disclose if the company or key management have been convicted of, or are the subject of any proceedings relating to a criminal offence or other office, a serious offence involving the activities of a criminal organization, found by any regulator or professional body to have committed professional misconduct; 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; failure to fulfill any obligations in any jurisdiction relating to the payment of taxes.

4. Technical Offer Requirements (NI & UNICEF)

4.1 Cover letter
4.1.1 Proponents are **required** 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 proponent's manufacturing facility has the capacity to produce Vitamin A in accordance with the technical requirements for the product as set out in this RFP.

4.2 NI-UNICEF Joint Pharmaceutical Product Questionnaire (and all supporting documents)
4.2.1 Proponents are **required** to complete the PPQ (Annex G) separately for each of the products for which they are submitting a proposal; i.e., proponents must submit a PPQ for each of the following products:
4.2.1.1 **Item 1:** 200,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES, 36-months shelf-life desired, 500 capsules per bottle
4.2.1.2 **Item 2:** 200,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES, 36-months shelf-life desired, 100 capsules per bottle
4.2.1.3 **Item 3:** 100,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES, 36-months shelf-life desired, 500 capsules per bottle
4.2.1.4 **Item 4:** 100,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES, 36-months shelf-life desired, 100 capsules per bottle
4.2.2 In annex G to the submitted PPQ(s), proponents are **required** to attach all supporting documents as specified in the checklist provided in the PPQ.

4.3 Proof of product shelf life

4.3.1 **Proof of product shelf life** as indicated and made in accordance to technical specifications as set out in Annex B. The Minimum Information Requirements for Stability Testing Protocols and Reports, Annex C to this RFP.

4.4 Letter of manufacturer certification

4.4.1 Proponents **will submit** the Letter of Manufacturer Certification provided in Annex H.

4.5 Table of ingredients, materials, and suppliers

4.5.1 Proponents are **required** to complete the Table of Ingredients, Materials and Suppliers in Annex I, listing all the ingredients and excipients composing the Vitamin A soft gelatin capsules and the primary and secondary packaging. Each product should be presented separately in its own table.

4.5.2 Any product offered **must meet** the product specification as outlined in Annex B. Conformity to this requirement may be verified by inspection. Proponents are required to disclose the names and addresses of intended material suppliers, and for ensuring that manufacturer(s) of all excipients used conform to all requirements stated in this RFP.

4.5.3 Proponents are strongly encouraged to provide copies of their agreements with API suppliers. This is not a mandatory requirement.

4.6 Halal certification

4.6.1 Proponents **must provide** a Certificate of Registration valid for the entire contract manufacturing period 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.

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

4.7 NI-UNICEF Joint Manufacturer Questionnaire

4.7.1 All proponents **must submit** a NI-UNICEF Joint Manufacturer Questionnaire (Annex N). Sub-contracted manufacturers (if any) involved in the manufacturing of products to NI and UNICEF **must** also complete a Manufacturer Questionnaire.

4.7.2 Proponents are also **required** to submit all supporting documents as required in the Manufacturer Questionnaire, including:

- A list of all products manufactured by the company and authorized for sale on the domestic market (stating country of manufacturing). Any other products held in other countries.
- Copy of site master file (PIC-S format).

5. Commercial Offer Requirements (NI Only)

5.1 Cover letter

5.1.1 Proponents **are required** 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 proponent's 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 Proponents **are required** to complete a Risk Assessment Register as set out in (Annex M).

5.2 Pricing table

5.2.1 The Pricing Table (Annex J) **must be completed and submitted** as part of the proposal.

5.2.2 Proponents **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:

- *Delivered at Place (DAP) UNICEF Supply Division Warehouse, Skagerakvej 6, 2100 Copenhagen, Denmark*

5.2.6 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 Proponents 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); early payment discounts (i.e. payment within a period of time less than NI and UNICEF's standard payment terms of 30 days net); trade discounts; any other unconditional discounts.

5.3.2 Should the proponent determine that a number of bottles other than the ranges specified in the Pricing Table (Annex J) result in a preferable pricing scheme, proponents are encouraged to submit a second, additional table specifying these alternative ranges.

5.4 Lead time

5.4.1 Proponents **are required** to indicate the realistic lead time for delivery of each product in the Lead Time Table (Annex K).

5.4.2 Delivery lead time is the period from the date of receipt of a purchase order by the proponent 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.

The DAP point is: UNICEF Supply Division Warehouse, Skagerakvej 6, 2100 Copenhagen, Denmark.

5.5 Delivery schedule

5.5.1 The Delivery Schedule (Annex K) **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 proponent, products with a shelf life of 24 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 Proponents **must submit** their most recent audited financial statements in support of their proposals.

5.7 Client references

5.7.1 All new proponents not previously contracted by NI **must submit** references from at least 3 clients within the last 2 years and with a minimum supply value of CAD $100,000 for each reference. Such references do not have to be directly related to vitamin A commodities. The format for submission of references is attached at (Annex L).

6. Submission Process

6.1 Questions from Proponents

6.1.1 All inquiries regarding this RFP **must be submitted** in writing by **June 7, 2019** to proposals@nutritionintl.org.

6.1.2 All questions posed and answers provided will be shared by email and posted on the NI website without attribution (see FAQ).

6.2 Confirmation of intent to submit

6.2.1 Proponents will inform NI by **June 17, 2019** of their intention to submit a proposal in response to this RFP. Confirmation should be sent by email to: proposals@nutritionintl.org.

6.3 Submission of offer

6.3.1 Proponents' complete Technical and Commercial Offers **must be received** no later than on **June 21, 2019 at 23:59 Ottawa EST.**

6.3.2 Submissions **must be sent** electronically via (email to proposals@nutritionintl.org).

6.3.3 All the attachments **must be labeled and referenced** corresponding to the document type and Annexes accordingly (E.g. Cover Letter, PPQ_Item1, etc.)

6.3.4 Offers **must be clearly marked** in the subject line as follows:

- PROPONENT'S NAME: TECHNICAL PROPOSAL (RFP: 12-01-0018)
- PROPONENT'S NAME: COMMERCIAL PROPOSAL (RFP: 12-01-0018)

6.3.5 Late proposals will not be accepted under any circumstances. Proposal submissions received after the deadline stated above will be disqualified.

6.4 Modifications and withdrawals

6.4.1. All modifications to proposals must be received by NI prior to the submission deadline. The proponent must clearly state the changes from the original proposal and indicate that the revised proposal supersedes the earlier version.

6.4.2. A proposal may be withdrawn by email by the proponent prior to the submission deadline.

6.4.3. Negligence on the part of the proposer confers no right for the withdrawal of the proposal after it has been opened.

6.4.4. Modifications and/or withdrawals **must be sent** by email to: proposals@nutritionintl.org.

7. Evaluation and Selection Process

7.1 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.

7.2 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.

7.3 **Joint NI –UNICEF Review of Technical Offers** - Once confirmed that the proponent has met the mandatory submission requirements of the RFP, Technical Offers will be evaluated by NI and UNICEF based on their compliance with the requirements set out in Section 4 of this RFP.

7.4 Any proponent that is deemed to have met the evaluation requirements for the Technical Offer will be pre-qualified as a supplier for Vitamin A for both UNICEF and NI. Pre-qualification does not guarantee that a proponent will receive an award.

7.5 **NI Review of Commercial Offers**. For the purposes of this RFP, submission of Commercial Offers by proponents are applicable to NI only. Any commercial offer and evaluation process involving pre-qualified proponents for UNICEF, will be conducted at a later date, as determined by UNICEF.

7.6 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 proponents);
- risk assessment and identification; and
- managerial and financial ability to complete the tasks set out in the RFP.

7.7 Proponents may be requested to correct errors or inconsistencies identified by NI during the proposal evaluation process. Proponents that do not comply with such requests within the timeframe communicated will be disqualified.

7.8 As needed, each proponent 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 proponent 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.

7.9 All the terms and conditions of this RFP and its Annexes, including the proponent's response to this RFP will form a part of the award unless otherwise negotiated. The proponent 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.

7.10 NI reserves the right to:

a. At any time prior to submission deadline, and for any reason, amend the RFP document. All proponents 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 proponent(s) without incurring any liability to the affected proponent(s).

c. Negotiate with one or more technically compliant suppliers and seek a best and final offer from technically compliant suppliers on any part 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 proponent's response. The proponent will provide reasonable cooperation with such verification.
h. Invalidate any proposal received from a proponent that, in the sole opinion of NI , has previously failed to perform satisfactorily or complete contracts or purchase orders on time, or that NI believe is not in a position to meet the requirements of the RFP.
i. 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 proponent at any time up. NI is not required to provide any justification, but will give notice prior to any such suspension of negotiations or withdrawal of award.

7.11 Notification: All proponents will be notified by the week of **July 19, 2019** of the outcomes of the process via email.

8. Terms and Conditions of Awards

8.1 Pre-Qualification of proponents

8.1.1 Any proponent that is deemed to have met the evaluation requirements for the Technical Offer will be technically pre-qualified as a supplier for Vitamin A for NI & UNICEF.

8.1.2 Pre-qualification does not guarantee that a proponent will receive an award.

8.2 Issuing of awards

8.2.1 Through the evaluation of this RFP, NI intends to enter into Long Term Arrangements (LTA) with selected proponents for a period of one, two, three or four years, with the option to extend for one additional year.

8.2.2 It is anticipated that LTAs for the full quantity of Vitamin A capsules required will be awarded to two to three selected proponents. NI and UNICEF will each separately issue LTAs in accordance with their internal procedures.

8.2.3 Delivery dates will be based on the Delivery Schedule as set out in (Annex K); precise dates will be specified in the LTA and/or Purchase Orders.

8.2.4 Attached to this RFP are sample NI LTA (Annex E), including General Terms and Conditions of Contract (Goods) (Annex F). By submitting a proposal in response to this RFP, the proponent is deemed to have confirmed its acceptance of the terms set out in these documents.

8.2.5 NI LTAs will be issued in Canadian Dollars (CAD).

8.2.6 Procurement of Vitamin A soft gelatin capsules is subject to the availability of funds from third-party donors).

9. List of Annexes

Reference Documents:
Annex A: Key References
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 Long Term Agreement (LTA) for Goods
Annex F: General Terms and Conditions of Contract (for Goods)

Required for Completion by all Proponents:
Annex G: NI-UNICEF Joint Pharmaceutical Product Questionnaire
Annex H: Letter of Manufacturer Certification
Annex I: Table of Ingredients, Materials, and Suppliers
Annex J: Pricing Table
Annex K: Delivery Schedule
Annex M: Risk Assessment Register
Annex N: NI-UNICEF Joint Manufacturer Questionnaire

Only Required for Completion by New Proponents:
Annex L: New Manufacturers Reference

10. Key Dates & Deliverables

Activity	Dates
RFP issued on NI Website:	***May 24, 2019***
Inquiries & Questions from Proponents regarding Technical & Commercial Submission process (via email) proposals@nutritionintl.org	***By June 7, 2019***
Confirmation by Proponents on Intent to Bid (via email) proposals@nutritionintl.org	***By June 17, 2019***
Deadline for Receipt of complete Technical and Commercial Offers	***June 21, 2019 at 23:59*** ***Ottawa EST.***
Notification by NI on outcome of the Evaluation Process (via email)	***By July 19, 2019***