Annex. 4
PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS

THIS DOCUMENT IS TO PROVIDE THE OFFERORS WITH THE PRODUCT(S) SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR THE PROCUREMENT OF COMMODITIES LISTED IN RFP **GHSC-PSM-TO1-2017-MCO-LUB-IDIQ**

Please note: All offerors must complete and submit Supplement 1- GHSC-QA Medical Device Questionnaire in accordance with the instructions provided in Supplement 2- Instructions for Creating a GHSC-QA Technical Questionnaire and Supplement 3- Instructions to Access and Upload Documentation to GHSC-QA SharePoint Site.

Eligibility Requirements and Product Specifications for Male Latex Condoms

1 Eligibility Requirements

Offerors and the products presented and delivered must fully comply with the following eligibility requirements:

- 1.1 Evidence of conformance with the current ISO 4074 Condom Standard and the WHO/UNFPA Male Condom Procurement Specification including:
  - 1.1.1 3 lots produced within the last 12 months and tested by an independent ISO 17025 accredited laboratory.
  - 1.1.2 Process control charts for airburst, freedom from holes, lubricant quantity, package seal integrity, and dimensions on lots produced within the last 12 months.
  - 1.1.3 Stability results demonstrating compliance with USFDA and/or ISO 4074 and the WHO/UNFPA Male Condom Procurement Specification
- 1.2 Evidence of USFDA 510(k) Pre-market approval
- 1.3 Evidence of CE Mark
- 1.4 Evidence of approval by National Drug Regulatory Authority (NDRA) in country of manufacture.
- 1.5 Manufacturing facility(s) certified to ISO 9001, 13485, and 14001 for each manufacturing site
- 1.6 Provide protein levels of the proposed condom
- 1.7 Provide nitrosamine types and levels of the proposed condom

- 1.8 Provide a copy of your site master file. The site master file must contain the following:
  - 1.8.1 Names of the principle contact person(s)
  - 1.8.2 Qualifications and experience of key managers
  - 1.8.3 List of manufacturing sites (locations/addresses)
  - 1.8.4 1List and Description of products produced (at each Site)
  - 1.8.5 Annual production capacity
  - 1.8.6 Description of manufacturing equipment
  - 1.8.7 Process Flow charts (showing all stages of production)
  - 1.8.8 Description of the Quality Management System

1.8.9 Description of Quality Assurance/Quality Control Departments
1.8.10 Description of finished Product handling procedures

1.9 Provide a copy of your product dossier (PD). The product dossier must contain the following:
1.9.1 Description of the product(s) proposed for the tender
1.9.2 Product Formulation with List of all raw materials
1.9.3 List the name, street address and country of each facility from which latex, foils and lubricant are obtained
1.9.4 Results of biocompatibility studies
1.9.5 Description of the production process – flowcharts (may be the same as in the SMF)
1.9.6 List of Internal Product Control Specifications & Procedures (in-process sampling/testing frequency)

1.10 Describe lot numbering system.

1.11 Provide a copy of the Medical Device Recall procedure.

1.12 List countries where the product is registered and currently marketed and include registration number and foil/brand.

1.13 If the product is not registered, list countries and foil/brand where registration process has started but not completed

1.14 Provide a list of references with contact information for past performance where similar goods and quantities were provided. (minimum of three 3). The provided references should have procured a substantial amount of product from the Offeror and should have had a relationship for an extended period of time with the Offeror.

1.15 Provide a sample of products being proposed. The required quantity is 30 gross from 3 different lots (10 gross for each lot). In case your offer also includes Colored/Scented condoms, one out of the required three lots (10 gross) should be for an offered colored/scented condom at your choice. Please carefully follow instructions in submitting samples to FHI360 (See annex A)

1.16 Provide a copy of your Business Continuity Plan / Disaster Recovery Plan.

1.17 Signed evidentiary proof of compliance with labor and child labor country of operation

2 Product Specifications

The manufacturer will supply to GHSC the quantities of male condoms in accordance with the specifications listed in this section which offer a minimum description of the supplies required.

2.1 **Materials-Latex**.

Condoms shall be manufactured from good quality natural rubber latex conforming to ASTM Specification D 1076 which is capable of meeting all the requirements and passing all the tests in this specification. The rubber latex shall be free of foreign contamination, embedded and surface particles, and discoloration. The condoms shall be free of excess powder or lubricant, and non-color condoms should be translucent and not liberate toxic or otherwise harmful substances under normal conditions of use. The condoms shall be in strict compliance with the current version of ISO 10993 Biological Evaluation of Medical Devices and other applicable requirements of the US Food and Drug Administration (USFDA) as provided in the USFDA's Guidance for Latex Male Condoms, and shall be in strict compliance with applicable portions of 21 CFR 1.

2.2 **Water extractable protein levels**

The recommended levels for soluble protein, as determined by the modified Lowry method, should be less than 50 µg/g. Manufacturers should take steps not to exceed this

level and should monitor production periodically. There is no specific standard for determining the protein levels in condoms. The methods described in ISO 12243, EN 455–3 and ASTM D5172 for determining the protein levels in medical gloves can be modified for condoms. Documentation recording protein levels should be available for review.

2.3 **Bioburden levels**
It is recommended that bioburden levels on packed condoms be maintained below 100 cfu and not be allowed to exceed 500 cfu. There should be an absence of Staphylococcus aureus and Enterobacteriaceae including Escherichia coli and Pseudomonas aeruginosa. Determination of microbial contamination should follow one of the methods described in ISO 4074 Annex G

2.4 **Nitrosamines**
It is recommended that manufacturers take steps to minimize the formation of nitrosamines. This can be done by ensuring that condoms are adequately leached and washed, by using minimum amounts of accelerators and by choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile. Testing shall be conducted in accordance to the current version of ISO 29941.

2.5 **Odor-**The condoms shall not give off an unpleasant odor when the package is opened at any time after manufacture and for the shelf-life of the product. A mild odor that dissipates quickly is acceptable. Reference the WHO/UNFPA Male Condom Procurement Specification for the odor evaluation scheme.

2.6 **Dressing and Compounding Materials**. Dressing materials (e.g. powders, and lubricants) and compounding materials (antioxidants, accelerators, vulcanizing agents and other additives including color pigments and fragrances shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body. Condoms shall NOT be dressed with talc, lycopodium spores water-based lubricants, oil-based lubricants or spermicides. All compounding and dressing materials shall be in strict compliance with the applicable portions of USFDA Guidance and 21 CFR 1.

2.7 **Shelf-Life** – The shelf life or the expiration date of the condoms shall be based on the compliance of three (3) production lots with the requirements of airburst properties, freedom from holes, and package integrity as specified in ISO 4074 after five years real-time aging at 30°C or after oven conditioning at (50±2)°C for 180 days. Standard colorless, unscented, non-flavored condoms must be labeled with a five (5) year expiration date. Colored and scented condoms must be labeled with not less than a four (4) year expiration date.

2.8 **Lot Sizes –** Each lot shall consist of units of product having a single type, style, class, size, and composition and shall be manufactured under essentially the same conditions and at essentially the same time, in compliance with its validated processes. Lot sizes shall be 3000 gross (432,000 condoms), smaller lot sizes are allowable to complete orders.

2.9 **Construction and Design.** Condoms shall have a smooth surface, and be essentially cylindrical in shape. The latex sheaths shall have an end open, and a visible shoulder

leading to a reservoir pouch at the tip. The open end shall have a thin ring consisting of several layers of latex contiguous with the sheath. Condoms shall have a wall thickness not less than 0.05 mm. The condom shall be easily unrolled at the time of the testing.

2.10 **Condoms** shall have parallel sides, without constrictions. The closed end of this style condom may be straight or expanded, according to the manufacturer's standard practice.

2.11 **Colored and/or Scented Condoms**. The colors and fragrances used must be food grade, non-toxic and non-sensitizing. Colors must be uniformly distributed, and non-leeching. Color and scented condoms are generally limited to yellow/banana, red/strawberry, and plain/vanilla. The Offeror must have specific USFDA 510(k) for each color/scent.

2.12 **Length and Width**. Condom lengths and lay-flat widths shall be as specified in Table I.

Table I: Length and Lay-Flat Width Requirements

	Classification	Length	Width
Parallel Sided	≥ 180 mm	53 ± 2 mm	(measured at 20 mm to 50 mm from the open end)
Parallel Sided	≥ 165 mm	49 ± 2 mm	(measured at 20 mm to 50 mm from the open end)

2.13 **Lubricant.** Condoms shall be dressed with powder and a fluid lubricant of the silicone type having a viscosity between 200 and 350 centistokes. The quantity of lubricant, including powder, in the individual package should not be less than 400 mg and no more than 700 mg. and shall be applied directly to the condoms in accordance with the manufacturer's standard practice. The condom shall be essentially transparent (clear) and the powder shall be evenly distributed with no visible accumulation.

2.14 **Identification Markings**. Each individual condom package shall be legibly marked to include the name or trademark of the manufacturer, the lot number, the un-coded date of manufacture, un-coded date of expiration, and production location including country. Where possible, the expiration date, batch number, manufacture date, manufacturer name, should be located in the center of the package.

3 Quality Assurance Provisions

3.1 **Responsibility for Inspection**. Unless otherwise specified in the Contract or purchase order, the Manufacurer will be responsible for the performance of all inspection requirements specified herein. USAID | GHSC–QA reserves the right to sample from the Manufacturer's facility and to perform or cause to be performed any of the tests and inspection set forth in this purchase description to assure that supplies and services conform to the prescribed requirements.

3.2 **Sampling.** Sampling plans shall be in accordance with the current edition of ISO 2859 - 1: and as listed in tables II-A and II-B. Statistically representative samples shall be taken from each production lot presented for evaluation. Condoms shall be selected randomly from each lot using a sampling protocol provided by USAID | GHSC–QA.

3.3 **Performance Tests.** Test methods used in product evaluation and their respective

acceptance criteria will be those specified by the current edition of ISO 4074 and as listed in Tables II-A and II-B.

3.4 **Color Fastness.** The method(s) used for assessing color fastness will be those used by the Contractor or agreed upon between the Contractor and USAID | GHSC–QA designated testing laboratory. The method must be sensitive enough to detect visual signs of color leeching or instability.

3.5 **Workmanship/Visible Defects**. Condoms shall be selected at random from each lot for determination of compliance with the requirements specified in Tables II-A and II-B. Condoms will be examined for defects in materials, construction, packaging, labeling, and overall serviceability using the description of possible defects in Table II-C. **Note**: The list of defects in Table II-C is not an exhaustive list. Other visible workmanship defects identified during the inspection process may be determined to detract from the physical appearance of the condom or affect its usability.

Table II-A

Sampling Plans, Test Methods, and Acceptance Criteria
53 mm Condoms

Attribute	Inspection Level	Test Method	Requirements
Dimensions Width: 51- 55 mm Thickness: ≥ 0.05 mm	S-2; AQL 1.0	ISO 4074	Length: ≥ 180 mm
Airburst Properties AQL 1.5	G-1 (at least Code M)	ISO 4074 Pressure: ≥ 1.0 kPa	Volume: ≥ 18.0 Liters
Individual Containers	G-I (at least Code M) AQL 0.4	ISO 4074	No visibly open seals
Workmanship/ Visible Defects	G-1 (at least Code M) Critical Defects: AQL 0.4 Non-Critical Defects AQL 2.5	Visual Inspection	Void of Visual Defects
Freedom from Holes AQL 0.25	G-1 (at least Code M) (Hang and Squeeze)	ISO 4074 of holes in condoms	Identify the presence
Lubricant Quantity	S-2; AQL 4.0	ISO 4074	*400 – 700 mg Lubricant and Powder
Package Integrity holes/voids in packages	S-3; AQL 2.5	ISO 4074	Identify the presence of
Color Fastness with Mfr.	S-3; AQL 0.4	As Agreed	No Leeching of colors
Packaging, Packing & Markings	S-3: AQL 2.5	Visual Inspection	As specified

*As specified in WHO/UNFPA Male Condom Procurement Specification

Table II-B
Sampling Plans, Test Methods, and Acceptance Criteria
49 mm Condoms

Attribute	Inspection Level	Test Method	Requirements
Dimensions	S-2; AQL 1.0	ISO 4074	Length: ≥ 165 mm Width: 47-51 mm Thickness: ≥ 0.05 mm
Airburst Properties	G-1 (at least Code M) AQL 1.5	ISO 4074	Volume: ≥ 16.0 Liters Pressure: ≥ 1.0 kPa
Individual Containers	G-I (at least Code M) AQL 0.4	ISO 4074	No visibly open seals
Workmanship/ Visible Defects	G-1 Critical Defects: AQL 0.4 Non-Critical Defects AQL 2.5	Visual Inspection	Void of Visual Defects
Freedom from Holes	G-1 (at least Code M) AQL 0.25	ISO 4074 (Hang and Squeeze)	Identify the presence of holes in condoms
Lubricant Quantity	S-2; AQL 4.0	ISO 4074	*400 – 700 mg Lubricant and Powder
Package Integrity	S-3; AQL 2.5	ISO 4074	Identify the presence of holes/voids in packages
Color Fastness	S-3; AQL 0.4	As Agreed with Mfr.	No Leeching of colors
Packaging, Packing & Markings	S-3: AQL 2.5	Visual Inspection	As specified

*****As specified in WHO/UNFPA Male Condom Procurement Specification

Table II-C
Workmanship and Visible Defects

Critical Visible Defects (Condoms); AQL 0.4

Defect	Description
Pleat/crease	The film sticks to itself, and the pleat/crease cannot be removed by gentle stretching of the adjacent film
Blister/bubble	An obvious circular or teardrop-shaped thin area with a well-defined border in the film. Such defects may break under pressure.
Large Coagulum	Rubber particles with any dimension of 1 mm or greater. These may cause the condom to fail in use.
Embedded and Surface Particles	Any particle with any dimension of 1 mm or greater. These may be dirt, hair, insects, powder granules, etc.
Bead defects	Faulty, missing or severely distorted beads.
Crack marks	Lines that penetrate the surface of the film, formed by shrinkage of the latex during drying. These do not include flow lines or marks from the mold.
Delamination	Areas where the individual layers of latex separate. (Condoms are formed by two or more dips in the liquid latex).
Thin Areas	Small areas of the condom (including the teat) that are visibly thin. These can show up as bulges with well-defined edges on the freedom-from-holes test. Condoms that look asymmetrical when filled with water are not necessarily in this category.

Non-Critical Visible Defects (Condoms and Packaging); AQL 2.5

Defects	Description
Embedded and Surface Particles	Particles with dimensions less than 1 mm that are visible to the naked or corrected eye.
Faulty bead (minor)	Uneven and partially distorted beads.
Uneven color	Minor streaking

Table II-C
Packing Defects

Individual Foil Pack Defects
Empty package
No lubricant
Lubricant leakage
Delamination of the packaging film
Discolored film and labels
Non-permanent marking
Missing Manufacturer's Name
Missing production location/Country
Incorrect/missing Lot number
Incorrect/missing Manufacture date
Incorrect/missing Expiration date
Difficult to open

Inner-box Defects
Empty or partially filled box
Discoloration and/or oil stains
Missing Manufacturer's Name
Missing production location/Country
Incorrect/missing Lot number
Incorrect/missing Manufacture date
Incorrect/missing Expiration date

Shipping Carton Defects
Empty or partially filled cartons
Non-permanent markings
Missing Manufacturer's Name
Missing production location/Country
Incorrect/missing Lot number
Incorrect/missing Manufacture Date
Incorrect/missing Expiration Date
Damaged cartons that may affect the integrity or quality of the condoms inside

4 Pre-Acceptance Inspection and Testing

4.1 Sampling.

4.1.1 The Manufacturer shall advise USAID | GHSC–QA when the completed monthly production is ready for inspection. Sampling visits shall be scheduled monthly or as needed to sample finished condom lots stored in the Manuafacturer's warehouse waiting for shipment. Samples shall be drawn only from finished product which has been tendered for acceptance.

4.1.2 The entire production shipment shall be quarantined until testing has been completed and disposition rendered.

4.1.3 One hundred (100) percent of the lots shall be sampled and evaluated for acceptance.

4.1.4 The samples will be tested in accordance with Table II-A, Table II-B and Table II-C (e.g., freedom from holes, airburst, package seal integrity, dimensions, lubricant quantity, packaging and workmanship).

4.1.5 Samples shall be taken in duplicate, with one set each for the Manufacturer and USAID | GHSC–QA. Sampling will be performed by USAID | GHSC–QA designated sampling agent who will submit the samples to the designated testing laboratory.

4.1.6 At the time of sampling, the Manufacturer shall supply USAID | GHSC–QA with the original finished laboratory product test results for each sampled lot.

4.1.7 The Manufacturer's chemical and physical test data shall be on record for each lot shipped to USAID | GHSC and shall be available to USAID | GHSC–QA upon request for a length of time equal to five (5) years from the time of acceptance.

5 Product Specifications and Test Methods.

This surveillance program shall comply with all product specifications and test procedures in effect at the time of contract award.

6 Compilation of Data.

At the completion of testing, all data from the designated testing laboratory shall be sent to USAID | GHSC–QA for verification and comparison with original test data obtained from the Manufacturer. USAID | GHSC–QA will prepare a detailed report along with supporting documentation and will simultaneously provide USAID | GHSC, and the Manufacturer with a copy of the findings.

7 Lot Disposition.

The recommendation to USAID | GHSC concerning the disposition of tested lots shall be determined by the results of tests performed by the designated testing laboratory. The testing provisions of the contract shall be applicable. USAID | GHSC–QA will inform the Manufacturer and USAID | GHSC of any tested and quarantined lots that are unacceptable for delivery; conduct failure investigations, and coordinate any re-tests (if appropriate).

8 Frequency of Monitoring.

USAID | GHSC–QA may increase or decrease the frequency of monitoring and level of testing when warranted by either a significant change in quality or at the sole discretion of USAID | GHSC–QA. The purpose is to maintain an acceptable level of confidence in compliance with contract requirements. For

purposes of monitoring, USAID | GHSC–QA will regularly prepare a Condom Supplier Status Report in order to track the performance of the Manufacturer.

9 Manufacturer Furnished Inspection Data

USAID | GHSC–QA will require that the Manufacturer provide a summary of the final inspection results for each lot available for delivery under this contract prior to shipment to USAID | GHSC–PSM. This summary shall include test results for dimensions, lubricant quantity, airburst volume/pressure, freedom from holes, package integrity, dip date and packaging/foiling line. Individual test reports shall be maintained by the Manufacturer, and shall be made available for inspection by USAID | GHSC–QA.

10 Post Acceptance Inspection

10.1 At any time within a sixty (60) month period (48 month for colored and scented condoms) after the product has been accepted, USAID | GHSC–QA and USAID | GHSC–PSM retain the right to re-examine any lot of condoms in accordance with USAID | GHSC–PSM contractual Terms and Conditions. In such an event, the quality assurance and testing provisions of the contract shall be those in effect at the time the condoms in question were accepted. If the complete condom manufactured lot is not available at the field location, a sampling plan using the total lot inventory at the field location shall be implemented in determining the appropriate random sample numbers for testing in lieu of the original manufacturer's lot size.

10.2 If the independent testing proves the product to be defective and the Manufacturer does not provide USAID | GHSC–QA contradictory test data within 15 calendar days, or such longer period as may be approved by USAID | GHSC–QA, then USAID | GHSC–PSM reserves the right to abide by the independent testing and will proceed with disposition and replacement of defective product by the manufacturer at no cost to USAID | GHSC–PSM.

11 Packaging and Packing

11.1 **Condom Packet.** Condoms shall be sealed in individual packets that can range from two inches (2") to two and one-quarter inches (2¼") square. Condom packets shall be constructed of a laminate that includes a layer of flexible aluminum foil having a minimum thickness of eight (8) microns and layers of plastic materials suitable for the mechanical protection of the aluminum foil and for printing and sealing. Sealed condom packets shall be provided in strips of four and perforated to facilitate easy separation/detachment of the individual packets. Individual packets shall be designed in such a way that the package can be open easily without damaging the condom. Sealed condom packets of aluminum foil and plastic laminate shall be impermeable to water, humidity, oxygen and ozone. Sealed condom packets of aluminum foil and plastic laminate shall be free of discoloration, de-lamination or any other degradation, when stored for at least (60) months under the storage conditions printed on the shipping carton.

11.2 **Inner Condom Boxes**. One hundred (100) condoms shall be neatly packaged in a one-piece, full telescope type box constructed from 22 point, unbleached, solid sulfate paperboard (SUS) or other box of similar color or durability. The inside dimensions of the box shall be approximately 8.750 inches long by 4.687 inches wide by 2.187 inches deep. Dimensions shall be adjusted as necessary to provide for a tight pack. The complete package shall be designed to protect the condoms against damage during shipment, handling and storage.

11.3 **Condom Packing**, packaged as specified in above, shall be packed, 30 inner boxes (3 layers of 10 each) in corrugated fiberboard shipping boxes made from weather resistant

fiberboard with a bursting strength of not less than 225 pounds per square inch. The box will be approximately 18.125"x 11.562" x 15" and weigh approximately 23 lbs. when filled. The box flaps shall be secured with water resistant adhesive applied to not less than 75 percent of the area of contact between the flaps or secured with three-inch (3") wide water resistant tape applied to the full length of the center seams and extending over the ends not less than three (3) inches.

11.4 **Marking**. Individually packaged condoms (foil packages) are to be marked with the manufacturer's logo and production location or name and production location. Condoms that require packaging with specific logos to meet program requirements or packaging with other logos which are mutually acceptable to both the manufacturer and the U.S. Government shall include, in addition to other appropriate marking, the manufacturer's logo and/or name and production location. The uncoded date of manufacture and expiry and the manufacturer's lot number shall be printed or stamped on each individual foil package. Any exceptions to the above will be specified in individual item descriptions which are designed to meet country labeling requirements.

11.5 The illustrative logos can be found in Annex A, and any other logo(s) mutually agreed by USAID | GHSC, and the Manufacturer(s), shall be imprinted on the individual foil.

11.6 **Boxes**. Each inner box (containing 100 condoms), packaged as specified above, and each shipping carton (containing 30 boxes of 100 condoms), packed as specified above, will be marked indicating:

(a) Condoms and size, (e.g., "Condoms, 53 mm"),
(b) Manufacturer's lot number,
(c) Uncoded date of Manufacture and Expiry - the numerals used for this on boxes of 3,000 shall be at least two inches in height -preceded by the words "Manufacture Date" and "Expiry Date" and as six digits, (e.g., 09/2009),
(d) Quantity, (e.g., "100 Condoms" or "3,000 Condoms"), and
(e) International symbols that convey the following messages: PROTECT CONTENTS AGAINST: Extreme Heat (over 40 degrees C), Moisture, Direct Sunlight or Fluorescent (Tube) Light.
(f) Up Arrow-Not required

11.7 **USAID Marking Requirements -**The manufacturer(s) will be responsible for ensuring that all export shipping cartons, whether shipped from the United States or from any other source country, carry the official USAID emblem.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping carton and the nature of the surface to be marked. The emblem on each export-shipping carton will be affixed in a manner which assures that the emblem will remain legible until the carton reaches the consignee.

The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Emblems will conform in design and color to samples available from USAID/Washington, D.C. and can be found at: http://www.usaid.gov/branding/
Emblems will be obtained by the manufacturer(s) at its expense in the quantity and type required. The manufacturer(s) will be required to affix USAID emblems in accordance with the marking requirements stated above.
A list of the emblem suppliers can be found at: http://www.usaid.gov/branding/suppliers.html

12 Registration Requirements
The Manufacturer will provide evidence of or obtain any necessary registrations and inform USAID | GHSC–PSM and GHSC-QA about the product registration status on an annual basis.

A list of countries to which similar products have been supplied in the past three years will be provided upon request, but this in no way excludes the use of these products in countries not identified. In those cases registration must be completed with-in one year of award. A list of countries where proposed product(s) is (are) registered must accompany the proposal. Inability to secure registrations may constitute failure to make progress and endanger performance of this contract. All registration cost will be borne by the manufacturer. USAID | GHSC will not support registration costs.

13 Stability
The manufacturer will agree to conduct accelerated product stability studies within the first year of the contract award, if necessary. The study protocol will be determined by USAID | GHSC–QA.

14 Participation in Proficiency Trials
The manufacturer will agree to participate in one or more condom proficiency trials each year of the contract.

15 The Offeror agrees to the Terms and Conditions for Quality Assurance Testing and Inspection in Annex B.

Product Description and Quality Requirements for Personal-Water Based Lubricant

Eligibility Requirements and Product Specifications for Water Based Personal Lubricants

2 Eligibility Requirements

Offerors and the products presented and delivered must fully comply with the following eligibility requirements:

15.1 Evidence of conformance with the specifications outlined in **TABLE I** below (WHO/UNFPA/FHi360 Advisory Note):
- 15.1.1 3 lots produced within the last 12 months and tested by an independent ISO 17025 accredited laboratory.
- 15.1.2 Process control charts for pH, viscosity, specific gravity on lots produced within the last 12 months.
- 15.1.3 Stability results demonstrating compliance with USFDA

15.2 Evidence of USFDA 510(k) Pre-market approval

15.3 Evidence of CE Mark

15.4 Evidence of approval by National Drug Regulatory Authority (NDRA) in country of manufacture.

15.5 Manufacturing facility(s) certified to ISO 9001, 13485, and 14001 for each manufacturing site

15.6 Provide a copy of your site master file. The site master file must contain the following:
- 15.6.1 Names of the principle contact person(s)
- 15.6.2 Qualifications and experience of key managers
- 15.6.3 List of manufacturing sites (locations/addresses)
- 15.6.4 List and Description of products produced (at each Site)
- 15.6.5 Annual production capacity
- 15.6.6 Description of manufacturing equipment
- 15.6.7 Process Flow charts (showing all stages of production)
- 15.6.8 Description of the Quality Management System
- 15.6.9 Description of Quality Assurance/Quality Control Departments
- 15.6.10 Description of finished Product handling procedures

15.7 Provide a copy of your product dossier (PD). The product dossier must contain the following:
- 15.7.1 Description of the product(s) proposed for the tender
- 15.7.2 Product Formulation with List of all raw materials
- 15.7.3 List the name, street address and country of each facility from which latex, foils and lubricant are obtained
- 15.7.4 Results of biocompatibility studies
- 15.7.5 Description of the production process – flowcharts (may be the same as in the SMF)
- 15.7.6 List of Internal Product Control Specifications & Procedures (in-process sampling/testing frequency)

15.8 Describe lot numbering system.

15.9 Provide a copy of the Medical Device Recall procedure.

15.10 Provide a list of references with contact information for past performance where similar goods and quantities were provided. (minimum of three 3)

Note: the provided references should have procured a substantial amount of product from the Offeror and should have had a relationship for an extended period of time with the Offeror.

15.11 Provide a sample of products being proposed. The required quantity is 500 sachets. Please carefully follow instructions in submitting samples to FHI360 (See annex B)

15.12 Provide a copy of your Business Continuity Plan / Disaster Recovery Plan.

15.13 Signed evidentiary proof of compliance with labor and child labor country of operation,

TABLE I

<table>
<tr><th colspan="2">Personal Lubricants - Summary Table of Product Guidelines (with Reference Test Methods)</th></tr>
<tr><th>Characteristic</th><th>References / Notes</th></tr>
<tr><td>Correct lubricant can be procured with either male or female condoms, if justified by programmatic requirements.</td><td>* Product must have a USFDA 510(k) status.
* Condom Compatibility Study (ASTM 7661 or equivalent) must be conducted to ensure applicability of lubricant. Protocol and Report must be submitted.
* Supplier must provide the stability study data that supports the product shelf life. Data for all conditions (i.e., 25ºC-60%RH, 30ºC-65/75%RH, and 40ºC-75%RH) must be provided as available.
* Summary reports for biocompatibility evaluation to ISO 10993 Part 1 (with a focus on parts 5 and 10) must be provided that disclose positive and negative controls used in the studies.</td></tr>
<tr><td><u>Water-based lubricants</u>
Osmolality must be 1200 mOsm/kg or less.</td><td>*Effectively equivalent to a 9.9% mass fraction or less of glycerol, or a 8.3% mass fraction or less of propylene content (if a mixture of glycols is used, a total limit of ca 8.3% mass balance is employed).
*Report % glycol level. Report osmolality levels (if available).
Reference method - USP <785> (Freezing Point Depression)</td></tr>
<tr><td>pH – 5.5 to 7.0</td><td>Reference method - USP <791></td></tr>
<tr><td>Absence of polyquaternary compounds, spermicides, medicinal, and other active substances</td><td>Preservatives are allowed – Provide a summary report for preservative effectiveness testing (Reference method – USP<51> Antimicrobial Effectiveness Testing)</td></tr>
<tr><td>Other Testing</td><td>An example certificate of analysis must be provided to outline all product release specifications (i.e., specific gravity, weight/volume in packet, visual inspection/appearance).
<table>
<tr><th colspan="3">Bioburden testing – must comply with the specifications listed below (USP <1111>) as evaluated by USP <61,62></th></tr>
<tr><th>Total Aerobic Microbial Count (cfu/g or cfu/mL)</th><th>Total Combined Yeasts/Molds Count (cfu/g or cfu/mL)</th><th>Specified Organisms</th></tr>
<tr><td rowspan="3">10^2</td><td rowspan="3">10^1</td><td>Absence of Pseudomonas aeruginosa (1g or 1 mL)</td></tr>
<tr><td>Absence of Staphylococcus aureus (1g or 1 mL)</td></tr>
<tr><td>Absence of Candida albicans (1g or 1 mL)</td></tr>
</table></td></tr>
<tr><td>Rheological Properties (Viscosity)</td><td>a) Test methods (with product specifications) used for viscosity characterization must be supplied that specifiy equipment, spindle type and size, spindle rotation speed, shear rate (if available), temperature, container inner dimensions (diameter and height) and volume of lubricant measured.
b) If available, provide viscosity measurements as outlined below (Reference - ASTM D2196-10 (Test Method B); ISO 2555):
*Brookfield Type Instrument (Spindle): LV (4) or RV (7), no guard leg – Report Instrument Type used.
*Sample Container – 120 mL Qorpak type vial (nominal dimensions – 42 mm inner diameter, 95-100 mm total inner height, 75 mm inner height required to obtained 120 mL nominal volume. Samples and standards are filled to 75 mm height, ensuring that no shaking occurs and that air bubbles are absent.
*Calibration Check using standard (~5000-20000 cps) measured at 25ºC (+/- 1ºC). Report all RPMs, viscosities, and temperatures readings, with certified calibration range for standard.
*Samples are stored for at least 60 minutes at the temperature to be measured (25ºC and 37ºC, +/-1ºC). Measurements are made at each possible RPM, proceeding step-wise from the lowest to the highest, back to the lowest. Report all RPMs, viscosities, and temperatures readings.
c) If available, provide viscosity measurements at shear rates (at least 5 different rates) ranging from 1 to 50 sec^{-1} using a cone/plate viscometer at 25ºC and 37ºC, +/-1ºC.</td></tr>
</table>

Annex A: Instructions for Submitting Samples

SAMPLES SUBMISSION FORM

Please carefully follow these instructions in submitting samples to FHI 360:

1. Complete all sections of the form below.
2. Email the completed form to FHI 360.
3. Reference the RFP/RFQ number on the labels and include copies of all relevant documents;
    a. Packing list
    b. Testing standards or other instructions (If applicable)
4. All samples must be sent in original packaging. Every package must be labeled **"For Analytical Testing Purposes Only. Not Intended for Human Use."**
5. Samples sent without proper labeling on all secondary packages may be denied entry by the US. Any shipment that is denied entry will be returned to the sender.
6. Please send the samples to the following address:

FHI 360
- **USA Laboratory-**
Product Quality and Compliance
2810 Meridian Parkway #160
Durham, NC 27713
USA
Tel: 1.919.544.7040 X 11665
Attn: Jeffery Tremelling - Associate Director, Product Quality and Compliance

Product details:							
Lot size:		Number of Lots:		Manufacture Date:		Expiration Date:	
Lot Numbers:							
Special Instructions:							

Vendor:				Date:	
Requested By:				Title:	
Tel:		Fax:		E-mail:	
Manufacturer:					
Manufacturer's Address:					

Annex B: SPECIAL CONTRACT TERMS AND CONDITIONS FOR QUALITY ASSURANCE TESTING AND INSPECTION

A. USAID | GHSC-QA shall have the right to sample, inspect, and test the Goods at the time(s) and location(s) indicated in the Order Form. In addition, Buyer shall have the right to sample, inspect, and test condoms/contraceptives and Pharmaceuticals in course of their manufacture and packaging.

B. Vendor shall provide all reasonable facilities for such sampling, inspection and testing at no cost to USAID | GHSC-QA.

C. USAID | GHSC-QA Will use its best efforts to complete sampling, testing and inspection as promptly as possible after the Goods are made available.

D. Buyer may, at its sole discretion
(1) require Vendor to repair or replace any nonconforming Goods, or re-perform of any non-conforming Services, at no increase in the Contract Price, and with all additional costs, including those arising from the handling and disposition of the non-conforming Goods and the sampling, inspection and testing of replacement Goods, for the account of Vendor; and/or

(2) exercise any other rights and remedies available to it under the Contract, or under applicable law and regulation, including, but not limited to, termination of the Contract, call of performance security, and/or assessment of excess re-procurement and other resulting costs.

Buyer will use its best efforts to exercise the foregoing rights within a reasonable time after a non-conformity is discovered and, to the maximum extent practicable, before any substantial change occurs in the condition of the non- conforming Goods, unless such change is due to their non-conformity.

E. Without prejudice to the foregoing, FAR 52.246-2, INSPECTION OF SUPPLIES -- FIXED-PRICE (AUG 1996), and FAR52.246-16, RESPONSIBILITY FOR SUPPLIES (APR 1984), shall apply to the Contract. Pursuant to these provisions—

If/when deemed necessary and appropriate, Buyer may by written notice to Manufacturer require pre-delivery sampling, inspection and testing of the Goods including, without limitation, physical inspections of the production, warehousing and other facilities involved, the product packaging and labeling; inspection and review of manufacturing records, Certificates of Analysis, analytical reports and documentation; and product sampling and testing by an independent testing facility. In such cases, Vendor will cooperate fully with USAID | GHSC-QA, the Sampling Agent and the testing facility and take such steps and supply such information as may be needed in order to ensure timely and effective quality assurance.

Only Goods that have successfully passed testing may be deemed to be ready for delivery in accordance with SCTC Article 5.

USAID | GHSC-QA may also direct post-delivery sampling, testing, and/or inspection of the Goods at any point in the chain of supply and distribution when it deems such action to be in the best interests of the Government. Manufacturer will fully cooperate with such measures as well. Prompt removal and replacement or correction (as applicable), for purposes of FAR 52.246-2 (g) and (h) shall be deemed, unless otherwise subsequently agreed by Buyer, to mean (10) business days after receiving notification of rejection of Goods or Services.