Bid Bulletin No. 1
July 2, 2019

Public Bidding 19-187-3

Supply and Delivery of Progestin Only Pill (POP)
for the Department of Health (DOH)

Issued pursuant to Sec. 22.5 of the IRR of R.A. 9184 to clarify and/or amend certain provisions in the Bidding Documents issued for this project, considering the issues raised and clarifications made by prospective bidders during the **Pre-bid Conference** held on **June 25, 2019**, likewise, respond to bidder's written queries received within the prescriptive period for filing.

After considering the recommendations and suggestions, the Procurement Service – Bids and Awards Committee III hereby decides to include, revise, amend, delete and/or adapt the following provisions of the bidding documents relative to the above-mentioned project:

A. AMENDMENTS

REFERENCE	BASES FOR AMENDMENT
SECTION III. BID DATA SHEET	
Page 40 XXX 12.1 (a)(i) Notwithstanding the above requirements, the bidder may opt to submit the following eligibility documents in lieu of the submission of the PhilGEPS Certificate of Registration (Platinum Membership): a. Business Registration; b. Mayor's Permit for <u>2019</u> c. ~~2017~~ **<u>2018</u>** Audited Financial Statement; d. Valid and current Tax Clearance;	To Amend the BDS Cluase 12.1 (a)(i) under Section III. Bid Data Sheet

For the purpose of this Bulletin and for better understanding of its contents, the following rules shall apply: (a) ~~double Strikeout~~ – denotes deletion; (b) <u>Underline</u> – denotes inclusion or new item/requirement; and "xxx" – denotes separation of phase/s being amended from the rest of the main text.

<table>
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<td>Page 44

29.2

For purposes of Post-qualification, the following document(s) are required to be submitted within five (5) calendar days from receipt of notice from the BAC:

9. The bidder shall submit any of the following whichever is applicable:

b. If the bidder is an Exclusive/Authorized Distributor or Dealer of the product items;

b.1 Certificate or Contract from the manufacturer must be provided as proof that the bidder is and Exclusive/Authorized Distributor or Dealer of the product/items or;

b.2 (1) Certificate or Contract from the from the manufacturer with the importer ~~and~~ <u>or</u> (2) Certificate or Contract from the importer with the distributor or dealer; or

XXX</td>
<td>To Amend the BDS Clause 29.2 under Section III. Bid Data Sheet</td>
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<td>SECTION V. SPECIAL CONDITIONS OF CONTRACT</td>
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<td>Page 67

XXX

10.2 ~~Progress Payment shall be made after acceptance of each delivery.~~ <u>No further instructions.</u>

XXX</td>
<td>To Amend the SCC Clause 10.2 under Section V. Special Conditions of Contract</td>
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<td>SECTION VII. TECHNICAL SPECIFICATIONS</td>
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XXX

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<tr><td>AGENCY SPECIFICATIONS</td><td>BIDDER’S STATEMENT OF COMPLIANCE</td><td>~~ACTUAL OFFER~~</td><td>~~REFERENCE~~</td></tr>
<tr><td>Progestin Only Pill (POP)</td><td><u>Brand:</u></td><td>~~Brand:~~</td><td></td></tr>
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<td>To Amend the Technical Specifications under Section VII. Technical Specifications

Revised Technical Specifications Form is labelled as Appendix “A” in this bid bulletin.</td>
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</table>

Page 72 Labeling Instructions: Standard labeling instruction as approved by PFDA pursuant to Administrative Order No. 2016-0008. In addition to the labeling requirement of PFDA: On each box, the following should be legibly imprinted or stickered with non-removable or permanent sticker label that is binding and with residue and tearing, if removed. Philippine Government Property – Department of Health NOT FOR SALE ~~/ RESALE~~ On each corrugated carton, should be legibly imprinted or stickered with non-removable or permanent sticker label that is binding and with residue and tearing, if removed. Philippine Government Property – Department of Health NOT FOR SALE ~~/ RESALE~~ Date of Manufacture:_____ Date of Expiry: _____ Batch/Lot No.:_____ Page 72 Additional Technical Documents: 4. The bidder shall submit any of the following whichever is applicable: b. If the bidder is an Exclusive/Authorized Distributor or Dealer of the product items; b.1 Certificate or Contract from the manufacturer must be provided as proof that the bidder is and Exclusive/Authorized Distributor or Dealer of the product/items or; b.2 (1) Certificate or Contract from the from the manufacturer with the importer ~~and~~ **<u>or</u>** (2) Certificate or Contract from the importer with the distributor or dealer; or XXX	To Amend the Technical Specifications under Section VII. Technical Specifications Revised Technical Specifications Form is labelled as Appendix "A" in this bid bulletin. .

Other Matters:

Technical Specifications	QUERY	RESPONSE
Labeling Instruction	1. Standard labeling instruction as approved by PFDA pursuant to Administrative Order No. 2016-0008. - On each box, the following should be legibly imprinted or stickered with non-removable or permanent sticker label that is binding and with residue and tearing, if removed. Philippine Government Property – Department of Health NOT FOR SALE / RESALE	Amended thru Bid Bulletin No. 1.
Recall and Disposal	2. In case of product recalls, damaged or expired medicines for replacement, the cost associated with the proper handling or pull out from health facilities where the medicines have already been distributed shall be borne by the Supplier.	The requirement is retained.
Delivery Period	3. One Hundred Twenty (120) calendar days (cd) upon receipt of approved Notice to Proceed (NTP).	The requirement is retained.
Shelf Life	4. Must be fresh commercial stock with a total shelf life of thirty six (36) months from the date of manufacture but not less than thirty four (34) months from the date of delivery.	The requirement is retained. Upon review of the cited DOH Manual of Procedures for the Procurement of Goods Vol. 2, 3.3.1 is just the minimum specification for shelf life, not a standard requirement. Likewise, Item II Guidelines of the Administrative Order No. 9-B, s.1998 on Guidelines for Acceptance of Drugs, Medicines, Reagents, and Other Medical Supplies Relative to the Expiration Date Specifies that: “the task of determining the ideal range of shelf life shall be delegated to the different Services and Programs based on previous requisition data, if there is any, and or from available literature from the Bureau of Foods and Drugs or other reputable source.” Based on the previous requisition data, the National

		Family Planning Program has been consistently requiring 36-34-month shelf life for the procurement of Progestin Only Pill (POP) in the previous years. Owing to the current challenges in the current distribution process of the DOH health goods i.e. delay of delivery of the PF commodities from the central warehouse down to the rural health units and barangay health stations, the 36-34-month shelf life could ensure that this commodity can still reach our target beneficiaries in full potency and efficacy. Further, the DPCB coordinated with the FDA regarding this matter. Currently, FDA has no existing guidelines prescribing ideal shelf life and reiterated that the Program should determine the shelf life requirement.
Additional Technical Requirements	5. (4) The bidder shall submit any of the following whichever is applicable: b. If the bidder is an Exclusive/Authorized Distributor or Dealer of the product items; b.2 (1) Certificate or Contract from the from the manufacturer with the importer and (2) Certificate or Contract from the importer with the distributor or dealer; or	Amended thru Bid Bulletin No. 1.

All other portions of the Bidding Documents affected by these amendments shall be made to conform to the same.

Amendments/inclusions/clarifications made herein shall be considered an integral part of the Bidding Documents.

The changes made in the Philippine Bidding Documents are deemed integrated in the terms and conditions for this project.

For the Bids and Awards Committee III

SGD
ENGR. EDWARD R. SADDI
Chairperson, DBM-PS BAC 3

APPENDIX "A"

Technical Specifications

LOT NO. 1 : Supply and Delivery of Progestin Only Pill (POP)

QUANTITY : **4,500,000 packs**

AGENCY SPECIFICATIONS	BIDDER'S STATEMENT OF COMPLIANCE
Progestin Only Pill (POP)	**Brand:**
Lynestrenol **500mcg (tablet)**	
Shelf Life: Must be fresh commercial stock with a total shelf life of thirty six (36) months from the date of manufacture but not less than thirty four (34) months from the date of delivery.	
Packaging Instructions: Primary Packaging – **1 cycle per blister pack (28 tablets)** Secondary Packaging – Standard packaging of the manufacturer as approved by PFDA including product insert or encryption imprint inside the box.	
Recall and Disposal 1. The supplier must ensure the quality of products and if there will be problems in the quality, the Supplier will recall and replace the products distributed in the regions, hospitals/treatment hubs, RHU, HC, BHSs based on Guidelines on Product Recall. FDA Circular No. 2016-008. 2. In case of product recalls, damaged or expired medicines for replacement, the cost associated with the proper handling or pull out from health facilities where the medicines have	

already been distributed shall be borne by the Supplier.	
Labeling Instructions: Standard labeling instruction as approved by PFDA pursuant to Administrative Order No. 2016-0008. In addition to the labeling requirement of PFDA: - On each box, the following should be legibly imprinted or stickered with non-removable or permanent sticker label that is binding and with residue and tearing, if removed. Philippine Government Property – Department of Health NOT FOR SALE - On each corrugated carton, should be legibly imprinted or stickered with non-removable or permanent sticker label that is binding and with residue and tearing, if removed. Philippine Government Property – Department of Health NOT FOR SALE Date of Manufacture:_____ Date of Expiry: _____ Batch/Lot No.:_____	
Additional Technical Documents: 1. Valid PFDA Certificate Product Registration (CPR) or Valid Extension. 2. PFDA License to Operate for Drug Distributors and Traders. 3. Product Insert/ Product Information or downloaded from the internet 4. The bidder shall submit any of the following whichever is applicable:	

a. If the bidder is a manufacturer, certificate that the bidder manufactures the product items; or b. If the bidder is an Exclusive/Authorized Distributor or Dealer of the product items; b.1 Certificate or Contract from the manufacturer must be provided as proof that the bidder is and Exclusive/Authorized Distributor or Dealer of the product/items or; b.2 (1) Certificate or Contract from the from the manufacturer with the importer or (2) Certificate or Contract from the importer with the distributor or dealer; or c. If the bidder is an agent of the exclusive distributor or dealer, the following must be provided: c.1 Certificate or Distributor/Dealership Agreement by the manufacturer with the importer/distributor or dealer; and c.2 Certification or Contract/Dealership Agreement between the distributor dealer and the bidder. 5. Certificate of Compliance to the Electronic Drug Price Monitoring System (EDPMS) issued by the Pharmaceutical Division (PD) of the DOH pursuant to DOH Administrative Order No. 2018-0020.	

I hereby certify that the statement of compliance to the foregoing technical specifications are true and correct, otherwise, if found to be false either during bid evaluation or post-qualification, the same shall give rise to automatic disqualification of our bid.

Name of Company	Signature Over Printed Name of Authorized Representative	Date