

Republic of the Philippines Department of Health

CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

BID BULLETIN NO. 4

12 December 2023

PROCUREMENT OF ETONOGESTREL IB NO. 2024-038

This Bid Bulletin is being issued to announce the new schedule of Submission and Opening of Bids previously set last 13 December 2023, amend or modify the bidding documents posted in the PhilGEPS and DOH websites for the above-mentioned project and to respond to Prospective Bidders (PBs) inquiries. This Bid Bulletin will form an integral part of the bidding document. Listed below are the corresponding modifications/changes:

1. New Schedule of Activity

A	From	To	V 7	
Activity	Date/Time	Date/time	Venue	
Submission and Opening of Bids	13 December 2023 9:00 AM	20 December 2023 9:00 AM	COBAC Conference Room, Ground Floor, Bldg. No. 6, Department of Health, Sta. Cruz, Manila, and/or through video conferencing or webcasting via Cisco Webex	

2. Response to Prospective Bidders' (PBs) inquiry:

Bidder	Particular	Inquiry	End-User Unit's (EUU) Response
Zuellig Pharma Corp.	Total ABC	Request for ABC Price Adjustment from 669.50 per rod to 741.00 per rod	Please see the attached revised Technical Specifications.
	Section VI. Schedule of Requirements	1st Tranche: 200,000 rods One Hundred Twenty (120) calendar days upon receipt of approved Notice to Proceed (NTP).	Please see attached revised Schedule of Requirements.
		2nd Tranche: 250,000 rods One Hundred Fifty (150) calendar days upon receipt of approved NTP.	

3. Quantity/Unit:

From	То
450,000 rods	406,570 rods

The revised Schedule of Requirements, and Technical Specifications are enclosed for the Prospective Bidders' reference and use.

All other provisions of the bidding documents which are not affected shall remain in force and in effect.

For guidance and information of all concerned

NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II

Undersecretary of Health COBAC-D Chairperson

Section VI. Schedule of Requirements

The delivery schedule expressed as calendar days stipulates hereafter a delivery date which is the date of delivery to the project site.

Item Number	Description	Quantity	Total ABC (PhP)	Delivery Site	Delivered, Calendar Days
1	Etonogestrel	406,570 rods	301,275,000.00	DOH Warehouse(s)	1st Tranche: 200,000 rods One Hundred Twenty (120) calendar days from receipt of approved Notice to Proceed (NTP).
					2nd Tranche: 206,570 rods One Hundred Fifty (150) calendar days from receipt of approved NTP.

Signature over Printed Name [date of signing]

In the capacity of:

Duly authorized to sign bid for and on behalf of:

[title or other appropriate designation]

[Name of Company]

[Complete office address]

[Contact No.] [Fax No.] [Email Address]

Technical Specifications

	- I			
	Republic of the Pl	nilippines		
Department of Health				
TECHNICAL SPECIFICATIONS				
Item No. 1	Etonogestrel	Quantity / Unit	406,570 rods	
Name of Manufacturer:		Country of Origin:		
Brand:				
Total ABC:	PhP301,275,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE		
A. Detailed Technical Specifications:				
1. Route of Administration: Subdermal				
2. Fori	n and Strength: 68mg sub-dermal implant			

- B. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:
- 1. Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

The CPR must be valid for the entire period of the award. If the CPR is about to expire, the supplier must have submitted a copy of an application of renewal to the FDA at least 3 months before the expiry date (a copy of the expiring CPR which is stamped with an "Extension of Validity" shall be submitted as proof); [AO 2019-0041]

2. Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA). *Provided, that the application for renewal was made timely as per DOH AO No. 2016-003:*

In case of expired LTO, the following copies may be submitted:

- (i) expired LTO;
- (ii) application for renewal with FDA document tracking number; and,
- (iii) Official Receipt as proof of payment of renewal of LTO
- 3. Product Insert/Product Information or downloaded from the internet and other manufacturer's unamended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate for cross-referencing statement of compliance to the technical specification in accordance to what is indicated in Technical Specifications;
- 4. Certification from the Manufacturer/Distributor/Importer/Wholesaler (as reflected in the Certificate of Product Registration of the product/s to be bid) that the Bidder is an authorized dealer or distributor of the product
- 5. Certificate of Compliance to the Electronic Drug Price Monitoring System (EDPMS) issued by either the Pharmaceutical Division (PD) of the DOH or DOH Regional Health Office/Centers for Health Development pursuant to DOH Administrative Order No. 2018-0020 and RA 9502 and its IRR;

In case of expired Certificate of Compliance to the EDPMS, refer to DOH Department

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS Item No. 1 Etonogestrel Quantity / Unit 406,570 rods Name of Manufacturer: Country of Origin: Brand: Total ABC: PhP301,275,000.00 PURCHASER'S SPECIFICATION STATEMENT OF COMPLIANCE

Circular (DC) No.2023-0001, "Interim Guidelines on the Certificate of Compliance to Electronic Drug Price Monitoring System for Government Procurement Activities for Drugs and Medicines."

- 6. Sworn Statement using the prescribed form.
- 7. Guarantee letter from Supplier to replace medicines with approved shorter shelf life when returned six (6) months before expiry date.

C. Replacement Instruction:

Medicines with approved shorter shelf life, replacement for fresh stocks shall be issued when returned six (6) months before the expiry date.

D. Upon delivery the following shall be complied with:

1. Shelf life: Must be fresh commercial stock with a total shelf life of sixty (60) months from the date of manufacture but not less than forty-eight (48) months from the date of delivery.

2. Packaging instructions:

a) Standard packaging of the manufacturer as approved by PFDA

3. Labeling instructions:

- a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.
- b) In addition to the labelling requirements of FDA:
 - i. On each **small box**, 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**

ii. 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.:	

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS Item No. 1 | Etonogestrel | Quantity / Unit | 406,570 rods Name of Manufacturer: | Country of Origin: Brand: Total ABC: PhP301,275,000.00 PURCHASER'S SPECIFICATION | STATEMENT OF COMPLIANCE

E. Product Recall & 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. 2016-012;
- 2. In instances of product recalls due to failures of suppliers and manufacturers to comply with standards of safety and quality, the cost associated with proper disposal/ destruction, handling or pull out from health facilities where these products have already been distributed shall be borne by the supplier (subject to the latest policy for disposal) (DOH Administrative Order (AO) No. 2019-0041).

Signature over Printed Name [date of signing]

In the capacity of: [title or other appropriate designation]

Duly authorized to sign bid for and on behalf of: [Name of Company]

[Complete office address]

[Contact No.]
[Fax No.]
[Email Address]