Republic of the Philippines
Department of Health

METRO MANILA CENTER FOR HEALTH DEVELOPMENT

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB 2022 – 088
PROCUREMENT OF 4,134 RODS ETONOGESTREL SUBDERMAL IMPLANT

This Supplemental/Bid Bulletin No. 1 is being issued to revise provisions/specifications in the Bidding Documents for a forecited project:

Revision and clarification to provisions/specifications in the Bidding Documents:
*No changes as stipulated in technical specifications.

Bidders are advised to use the following attached forms and submit together with all required documents for the submission of bids on 13th day of December 2022, 9:00 AM:

This Supplemental/Bid Bulletin No. 1 shall form an integral part of the Bidding Documents. All other provisions indicated in the bidding documents which are not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 6th day of December 2022 in MMCHD

Approved by:

ALELI ANNIE GRACE P. SUDIACAL, MD, MPH
Director III / BAC Chairperson

Republic of the Philippines

Department of Health

Metro Manila Center for Health Development

TECHNICAL SPECIFICATIONS

Item No. 1	**PROCUREMENT OF 4,134 RODS ETONOGESTREL SUBDERMAL IMPLANT**	Qty./Unit	4,134 ROD
Name of Manufacturer:		Country of Origin	
Brand:		Model: (if applicable)	
ABC: P 6,201,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	

SPECIFICATIONS:

ETONOGESTREL SUBDERMAL IMPLANT

> 68 mg subdermal implant

> **Primary Packaging**- each box contains 1 unit of sin gled-rod contraceptive implant preloaded in a sterile disposable applicator, 1 patient card, 1 physician card and 1 product information insert

> **Secondary Packaging** - standard packaging of the manufacturer as approved by PFDA including product insert or encryption/ imprint inside the box

Shelf Life

1. Must be fresh commercial stock with a total shelf life of Sixty (60) months upon manufacture but not less than forty two (42) months from the date of delivery.

Labelling Instructions:

>Standard labeling instruction as approved by PFDA pursuant to Administrative Order No. 2016-0008

In addition to the labelling requirements of FDA

a. On each box the following should be imprinted or stickered with non-removable or permanent sticker or label that is binding, and with residue and tearing, if removed;

Philippine Government Property – Department of Health

Date of Manufacture:

Date of Expiry:

Batch/Lot No.:

Delivery Schedule:

>60-90 calendar days (CD)

Delivery Site:

>DOH-MMCHD Pasig Warehouse

Additional Technical Documents:

a. Valid PDFA Certificate of Product Registration (CPR) or Valid Extension
b. PDFA License to Operate (LTO) for Drugs Distributors and Traders
c. Product insert/ Product Information
d. Certificate from the manufacturer/main distributor that Bidder is an authorized dealer/exclusive distributor of the product

FDA Test Analysis:

>The minimum number of the sample units required for each test analysis of delivered medicines shall be based on the PFDA Circular 2014-014

ADDITIONAL REQUIREMENT TO BE SUBMITTED BY THE SINGLE/LOWEST CALCULATED BIDDER (SCB/LCB) AS PART OF POST QUALIFICATION: 1. One (1) original sample of manufacturer's product to be submitted and returned after evaluation. The sample submitted and approved during the evaluation shall be the same item to be delivered upon award of contract. Prototype of the labelling instruction must be part of the sample submitted however, the technical specifications of the labelling instruction of the product must be complied upon delivery.	