Republic of the Philippines
DEPARTMENT OF HEALTH
Metro Manila Center for Health Development

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-128
IB#2024-128 Procurement of 4 FDC (Rifampicin 150mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol HCI 275 mg)

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

1. Query during Pre-bidding Conference:		
Technical Specifications	**Query**	**Response of the End User Unit**
30 calendar days after receipt of approved P.O./NTP45	45 calendar days after receipt of approved P.O./NTP	45 calendar days after receipt of approved P.O./NTP GRANTED

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 22nd day of August 2024, 9:00 AM:**

This Supplemental/Bid Bulletin No. 1 shall be integral to the Bidding Documents. All other provisions indicated in the bidding documents not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 13th day of August 2024 in MMCHD

Approved by:

JEREMIAS FRANCIS Y. CHAN, MD
Licensing Officer V / BAC Chairperson

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TECHNICAL SPECIFICATIONS

4 FDC (Rifampicin 150mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol HCI 275 mg)	Qty./Unit	450,000 tablets

Name of Manufacturer:	Country of Origin (if applicable)
Brand:	Model: (if applicable)
ABC: P 3,600,000.00	

PURCHASER'S SPECIFICATION	STATEMENT OF COMPLIANCE
a. Specifications: 4 FDC (Rifampicin 150mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol HCI 275 mg) *30 calendar days after receipt of approved P.O./NTP*	

B. Upon delivery, the following shall be complied with:

1. Shelf Life:

Must have a minimum shelf life of twenty-four (24) months from the date of manufacture but not less than eighteen (18) months from the date of delivery.

2. Packaging Instructions:

Standard packaging of the manufacturer as approved by PFDA, including product insert or encryption/imprint inside the box

3. Labeling instructions:

1.Standard Labelling instructions as approved by PFDA pursuant to Administrative Order no. 2016-008

2.In addition to the labelling requirements of the PFDA:

a. On each blister pack/foil strip and box, the following should be legibly imprinted or stickered using a permanent, non-removable sticker/label that is binding and will leave residue and ripping if removed.

"Philippine Government Property-Department of Health"

NOT FOR SALE

b. On each small and bigger box/carton, the following should be legibly imprinted or stickered with a non-removable or permanent sticker or label that is binding and will leave residue and rip if removed

"Philippine Government Property-Department of Health"

NOT FOR SALE

Date of Manufacture: _____
Date of Expiry:_____
Batch/Lot No.:_____

C. Additional Requirements to be attached to the Technical Specifications form arranged, numbered, and tabbed as enumerated below:

1. Valid and current Certificate Product Registration (CPR) , Certificate of Medical Device Registration (CMDR), or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA);

The CPR must be valid for the entire period of the award. If the CPR/CMDN/CMDR 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

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TECHNICAL SPECIFICATIONS

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proof); [AO 2019-0041]

2. Valid and current License to Operate (LTO) for Medical Device Exporter / Trader /Importer / Distributor / Wholesaler issued by Philippine Food and Drugs Administration (PFDA)

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 a cross-referencing statement of compliance to the technical specification in accordance to what is indicated in Technical Specifications;

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 products/item or

b. If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, a Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items or

c. If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:

i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and

ii. Certificate/Contract between the distributor/dealer and the bidder.

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a. If the bidder is a manufacturer, certificate that the bidder manufactures the products/item or

b. If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, a Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items or

c. If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:

i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and

ii. Certificate/Contract between the distributor/dealer and the bidder.