



SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-111

Procurement of 4 FDC (Rifampicin 150mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol HCl 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
Delivery Period – 30 calendar days	Delivery Period – 30 to 60 calendar days – for clarification with end user	Delivery Period –60 calendar days –

The MMCHD will hold an official activity on July 9, 2024. Suppliers who would want to get the bidding documents are welcome to visit our BAC Secretariat Office until July 8, 2024.


Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 10th day of July 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 2nd day of July 2024 in MMCHD

Approved by:


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

Republic of the Philippines
Department of Health
Metro Manila Center for Health Development

TECHNICAL SPECIFICATIONS (UPDATED)

Item No. 1	4 FDC (Rifampicin 150mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol HCl 275 mg)	Qty./Unit	468,142 tablets
Name of Manufacturer:		Country of Origin	
Brand:		Model: (if applicable)	
ABC: P 3,745,136.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
Specifications: 4 FDC (Rifampicin 150mg + Isoniazid 75 mg + Pyrazinamide 400 mg + Ethambutol HCl 275 mg)			

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 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 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.

C. Additional requirement by the Lowest/Single Calculated Bid (L/SCB) 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 contract award. The prototype of the labeling instruction must be part of the sample submitted; however, the technical specifications of the labeling instruction of the product must be complied with upon delivery.
2. L/SCRB shall pick up the Contract and Notice to Proceed issued in its favor within three (3) calendar days from receipt of notice. An electronic mail shall constitute an official notice to the Bidder.
3. Refusal to sign and accept the Award or enter into a contract without justifiable reason may be grounds for imposing administrative sanctions under Rule XXIII of the Revised IRR of RA 9184.
4. The registered company name and email address must be consistent and should reflect on all documents to be submitted.
5. Request for extension should be submitted before the lapse of the original delivery date. The maximum allowable extension shall not be longer than the Original Delivery term.
6. Delivery through courier service is not allowed.

D. 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.: _____

. Product Recall & Replacement:

1. The supplier must ensure the quality of products. If there are 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.