Republic of the Philippines
Department of Health

METRO MANILA CENTER FOR HEALTH DEVELOPMENT

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-055

Procurement of Protein Purified Derived Solution

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:	
ORIGINAL TECHNICAL SPECIFICATIONS	**AMENDED**
Tuberculin Purified Protein Derivative 5 TU/0.1ml Injection Multiple Dose Vial 5ml	Tuberculin Purified Protein Derivative 5 TU/0.1ml Injection Multiple Dose Vial ~~5ml~~ ***1ml***

Bidders are advised to use the following attached forms and submit them together with all required documents for the submission of bids on the 25th day of March 2024, 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 that are not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 15th day of March 2024 in MMCHD

Approved by:

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

Section VII. Technical Specifications

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

TECHNICAL SPECIFICATIONS

Item No. 1	Procurement of Protein Purified Derived (PPD) Solution	Qty./Unit	1,0000 vials
Name of Manufacturer:		Country of Origin	
Brand:		Model: (if applicable)	
ABC: P 1,000,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
A.SPECIFICATIONS Tuberculin Purified Protein Derivative 5 TU/0.ml Injection Multiple Dose Vial *1ml* Protect from light Tuberculin/PPD Solutions can be adversely affected by exposure to light Transport at 2 to 8 degrees Celsius (35 to 46 degrees Fahrenheit) Do not Freeze Enough antigen for 50 test per vial			

B. 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) 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) sample to be submitted for evaluation. The sample submitted and approved during the evaluation shall be the same sample to be delivered upon award of contract. 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:

The product must have a minimum shelf life of eighteen (18) months remaining at the time of delivery.

2. Packaging Instructions:

A. Standard Packaging of the manufacturers as approved by the PFDA.

3. Labeling instructions:

1. Standard Labeling instruction as approved by PFDA pursuant to Administrative Order No. 2016-0008

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

a. On each kits, the following should be legibly imprinted or stickered:

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.

2. In case of the product recalls, damage or expired medicines for replacement, the costs associated with the proper handling or pull out from health facilities where the medicines have already been distributed shall be borne by the Supplier.

_____

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]