



SUPPLEMENTAL/ BID BULLETIN NO. 1

IB No. 2025-012
Procurement of Biphasic Insulin with Insulin Syringe
(EARLY PROCUREMENT ACTIVITY)

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

| Query during Pre-bidding Conference: | | |
|--------------------------------------|--|--|
| Technical Specification | Query | Response of the End User Unit |
| | With ten (10) insulin syringe per vial | With ten (10) insulin syringe per vial |

Furthermore, this is to inform bidders that the bidding will be moved on the **29th of November, 2024** instead of November 27, 2024 due to lack of quorum

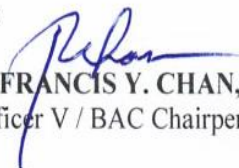
Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 29th day of November 2024, 9:00 AM:**

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 20th day of November 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 | | | |
|--|--|-----------------------------------|-----------|
| Item No. 1 | Biphasic Insulin with Insulin Syringe | Qty./Unit | 8,000 pcs |
| Name of Manufacturer: | | Country of Origin (if applicable) | |
| Brand: | | Model: (if applicable) | |
| ABC: P 2,400,000.00 | | | |
| PURCHASER'S SPECIFICATION | | STATEMENT OF COMPLIANCE | |
| <p><u>SPECIFICATIONS:</u></p> <p>Route of Administration: Subcutaneous (SC)</p> <p>Form and Strength: 70% isophane suspensions + 30% soluble insulin 100 IU/ml, 10 ml (recombinant DNA)</p> <p><i>With ten (10) insulin syringe per vial</i></p> <p>Delivery Period: Thirty (30) to Sixty (60) calendar days after receipt of the Notice to Proceed</p> <p>Delivery Place: DOH MMCHD Pasig Warehouse</p> | | | |
| <p>B. Upon delivery, the following shall be complied with:</p> <p>1. Shelf life:</p> <p>Must be fresh commercial stock with a total shelf life of twenty-four (24) months from the date of manufacture but not less than eighteen (18) months from the date of delivery</p> <p>2. Packaging Instructions:</p> <p>Standard packaging of the manufacturer as approved by the FDA</p> <p>Recall and Disposal</p> <ol style="list-style-type: none"> 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/BHSs bases on Guidelines on Product Recall, FDA Circular No. 2016-012 2) In case of product recalls, damage or expired medicines due to 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 <p>Labeling instructions:</p> <p>Standard labelling instruction as approved by FDA pursuant to Administrative Order No. 2016-0008</p> <p>In addition to the labeling requirements of the PFDA:</p> <ol style="list-style-type: none"> a. On each blister pack/foil strips and box, 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

- b. On each bigger box/corrugated carton, the following 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 Number: _____

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 Valid Extension issued by the 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 an expired Certificate of Compliance to the EDPMS, refer to DOH Department 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."

D. Additional requirement by the Lowest/Single Calculated Bid (L/SCB) as part of post qualification:

1. You are requested to submit within (5) five days upon receipt of this notice three (3) copies of all documents needed for Post Qualification of the following documents:
 - a. Eligibility Documents
 - i. (Mayor's Permit (latest annual and quarterly)
 - ii. SEC/DTI Registration,
 - iii. Tax Clearance)
 - b. Certificate of Registration from BIR
 - c. Income Tax Returns – latest payment
 - d. Bid Bulletin
 - e. Product Sample /Brochure
 - f. Authority from the Manufacturer to Distribute the Product
 - g. License to Operate
 - h. And other documents stated in BDS
 - i.
2. One (1) original sample of the 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.

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)

Section VI. Schedule of Requirements

The delivery schedule expressed as weeks/months 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, Weeks/Months |
|--------------------|---------------------------------------|------------------|------------------------|---------------------------------|---|
| | Biphasic Insulin with Insulin Syringe | 8,000 pcs | P 2,400,000.00 | DOH-MMCHD Pasig Warehouse | 30 -60 calendar days after receipt of approved P.O./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]