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

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-120
Procurement of Risperidone

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
Shelf Life: must be fresh commercial stock with a total shelf life of 24 months from the date of manufacture but not less than 18 months from the date of delivery	Shelf Life: must be fresh commercial stock with a total shelf life of 24 months from the date of manufacture but not less than 18 months from the date of delivery with a guarantee letter – for clarification	Shelf Life: must be fresh commercial stock with a total shelf life of 24 months from the date of manufacture but not less than 18 months from the date of delivery.- GRANTED Recall and Replacement For stocks with less than two (2) months remaining shelf life, the winning bidder will replace it with at least six (6) months shelf life and deliver such within two (2) weeks. The replacement of risperidone is continuous until total consumption.

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 7th 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 31st day of July 2024 in MMCHD

Approved by:

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

TECHNICAL SPECIFICATIONS			
Item No. 1	Risperidone	Qty./Unit	39,999 tablet
Name of Manufacturer:		Country of Origin (if applicable)	
Brand:		Model: (if applicable)	
ABC: P1,199,970.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
A. Specifications Route of Administration: Oral Form and Strength: 2mg Shelf Life: must be fresh commercial stock with a total shelf life of 24 months from the date of manufacture but not less than 18 months from the date of delivery. Delivery Period: 30-60 calendar days after receipt of approved P.O./NTP DOH-MMCHD Pasig Warehouse			
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. 5. Certificate of compliance to the Electronic Drug Price Monitoring System (EDPMS) issued by the Pharmaceutical Division of DOH pursuant to DOH Administrative Oder no. 2018-0020	
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 and will 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.	
D. Upon delivery, the following shall be complied with: Packaging Instructions: 1. Primary Packaging: blister pack/slip 2. Secondary Packaging: 30 tablets per small box (DOH Treatment Pack) 3. Tertiary Packaging: 1000 Treatment packs per corrugated carton 4. Labeling instructions: 1.Standard labelling instruction as approved by FDA pursuant to Administrative Order no.2016-006. 2.On each blister pack/foil strip and box, the	

following should be 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 3.On each bigger box/corrugated carton, the following should be 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 Date of Manufacture:_____ Date of Expiry:_____ Batch/Lot No._____		
E. Product Recall & Replacement: 1. The supplier must ensure the quality of products. If there are problems with the quality, the supplier will recall and replace the products distributed in the regional hospitals/treatment hubs/RHU/HC/BHSs based on the guidelines on product recall, FDA Circular No. 2016-012. 2. In case of product recalls, damage, or expired medicines that need to be replaced, the supplier shall bear the costs associated with the proper handling or removal from health facilities where the medicines have already been distributed. 3. *For stocks with less than two (2) months remaining shelf life, the winning bidder will replace it with at least six (6) months shelf life and deliver such within two (2) weeks. The replacement of risperidone is continuous until total consumption*		