Republic of the Philippines
Department of Health
METRO MANILA CENTER FOR HEALTH DEVELOPMENT

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB NO. 2024-041
Procurement of Fluoride Varnish (SHORT OF AWARD)

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

Revision and clarification to provisions/specifications in the Bidding Documents:
ORIGINALTECHNICAL SPECIFICATIONS
No changes stipulated in Technical Specifications

Bidders are advised to use the following attached forms and submit together with all required documents for the submission of bids on November 20, 2023, 9:00 AM

This Supplemental/Bid Bulletin No. 1 shall form part of the Bidding Documents. Any provisions in the Bidding Documents inconsistent herewith is hereby amended, modified and superseded accordingly.

For guidance and information of all concerned.

Issued this 14th day of November, 2023 in MMCHD.

SGD.
PRETCHELL P. TOLENTINO, MD, MCHM
Director III / BAC Chairperson

Section VII. Technical Specifications

<table>
<tr><td colspan="4">Republic of the Philippines
Department of Health
Metro Manila Center for Health Development

TECHNICAL SPECIFICATIONS</td></tr>
<tr><td>Item No. 1</td><td>Fluoride Varnish</td><td>Qty./Unit</td><td>550 sachets</td></tr>
<tr><td colspan="2">Name of Manufacturer:</td><td colspan="2">Country of Origin</td></tr>
<tr><td colspan="2">Brand:</td><td colspan="2">Model: (if applicable)</td></tr>
<tr><td colspan="2">ABC: P 1,540,000.00</td><td colspan="2"></td></tr>
<tr><td colspan="2">PURCHASER’S SPECIFICATION</td><td colspan="2">STATEMENT OF COMPLIANCE</td></tr>
<tr><td colspan="2">Specifications:

White Varnish with 5% sodium fluoride varnish, single dose

22,600 ppm fluoride and tri-calcium phosphate (TCP)

0.5ml single dose

Delivery Period:
45-60 calendar days from the receipt of approved NTP

Delivery Place: MMCHD Pasig Warehouse</td><td colspan="2"></td></tr>
<tr><td colspan="4">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</td></tr>
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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:

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.

2. Packaging Instructions:

3. Standard Packaging of the manufacturer as approved by PFDA.
4. 20 sachet per box

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 blister pack and box the following shall be legibly imprinted or

stickered using a permanent, non-removable sticker/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 imprinted or stickered with non-removable or permanent sticker or 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 No._____

E. 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.