Republic of the Philippines
Department of Health
CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

BID BULLETIN NO. 1
26 April 2021

PROCUREMENT OF COTRIMOXAZOLE, CO-AMOXICLAV AND CETIRIZINE
IB NO. 2021-174

This Bid Bulletin is being issued amend or modify the posted bidding document in the PhilGEPS and DOH websites. This Bid Bulletin will form an integral part of the bidding document for the Procurement of Cotrimoxazole, Co-Amoxiclav and Cetirizine under IB No. 2021-174. Listed below are the corresponding modifications/changes.

a) ***Technical Specifications***

From	To
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 Expired CPR with Extension of Validity issued by Philippine Food and Drug Administration (PFDA); Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 July 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A] XXX	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 Expired CPR with Extension of Validity issued by Philippine Food and Drug Administration (PFDA); Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on ***01 January to 30 June 2021***, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A] XXX

b) ***Checklist of Technical and Financial Documents***

From	To
I. TECHNICAL COMPONENT ENVELOPE ☐ (i) Original duly signed Omnibus Sworn Statement (OSS);	**I. TECHNICAL COMPONENT ENVELOPE** ☐ (i) Original duly signed Omnibus Sworn Statement (OSS);

and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder. XXX	**and** if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder. *Note: In consideration of the limited access to financial institutions, regulatory and other offices, as well as the implementation of government restrictions on transport and travel, submission of Unnotarized Bid Securing Declaration and Omnibus Sworn Statement are acceptable for procurement activities during a State of Calamity, or implementation of community quarantine or similar restrictions declared or being implemented either in the locality of the PE or of the Bidder, subject to compliance therewith after award of contract but before payment (GPPB Circular 09-2020)* XXX
III. ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN THE TECHNICAL SPECIFICATIONS FORM: ☐ (a) Valid and current Certificate Product Registration (CPR) or Expired CPR with Extension of Validity issued by Philippine Food and Drug Administration (PFDA); Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 July 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A] XXX	**III. ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN THE TECHNICAL SPECIFICATIONS FORM:** ☐ (a) Valid and current Certificate Product Registration (CPR) or Expired CPR with Extension of Validity issued by Philippine Food and Drug Administration (PFDA); Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on ***01 January to 30 June 2021,*** are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A] XXX

The revised Technical Specifications Form and Checklist of Technical and Financial Documents are enclosed for the Prospective Bidder's reference and use.

All other provisions of the bidding documents which are not affected shall remain in force and in effect.

For guidance and information of all concerned.

(SGD.)
NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II
Assistant Secretary of Health
Chairperson, COBAC-A

Technical Specifications

Republic of the Philippines
Department of Health
TECHNICAL SPECIFICATIONS

Item No. 1	**Cotrimoxazole Tablet**	Quantity / Unit	**300,000 tablets**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 1: **PhP375,000.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. Detailed Technical Specifications: 1. **Route of Administration**: Oral 2. **Form and Strength**: a) Tablet b) 800 mg sulfamethoxazole + 160 mg trimethoprim	

B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1) Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

2) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

   Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 June 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

3) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

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, Certificate or Contract from the manufacturer or importer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Cotrimoxazole Tablet**	Quantity / Unit	**300,000 tablets**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 1: **PhP375,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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. Contract between the distributor/dealer and the bidder.

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 expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

6) Sworn Statement *using the prescribed form.*

C. <u>Upon delivery the following shall be complied with:</u>

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:

a) Standard packaging of the manufacturer as approved by PFDA.

3. Labeling instructions:

a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.

b) In addition to the labeling requirements of FDA:

1. On each blister pack, the following shall 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

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Cotrimoxazole Tablet**	Quantity / Unit	**300,000 tablets**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 1: **PhP375,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

2. On each small box and corrugated carton, the following shall 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.: _____

D. Product Recall & Disposal:

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal);

2. In cases of expired drugs, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Services (AS) of the DOH health facility, subject to compliance to applicable laws.

_____
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]

Technical Specifications

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 2	**Cotrimoxazole Suspension**	Quantity / Unit	**10,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 2: **PhP270,400.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. Detailed Technical Specifications: 1. **Route of Administration**: Oral 2. **Form and Strength**: a) Suspension b) 200 mg sulfamethoxazole + 40 mg trimethoprim per 5mL suspension, 70 mL			

B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1) Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

2) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

   Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 June 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

3) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

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, Certificate or Contract from the manufacturer or importer 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:

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 2	**Cotrimoxazole Suspension**	Quantity / Unit	**10,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 2: **PhP270,400.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
ii. Contract between the distributor/dealer and the bidder.

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 expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

6) Sworn Statement *using the prescribed form.*

C. <u>Upon delivery the following shall be complied with:</u>

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:**

Standard packaging of the manufacturer as approved by PFDA.

3. **Labeling instructions:**

a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.

b) In addition to the labeling requirements of FDA:

1. On each bottle, the following shall 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

2. On each small and bigger box, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed:

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 2	**Cotrimoxazole Suspension**	Quantity / Unit	**10,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 2: **PhP270,400.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

Philippine Government Property – Department of Health
NOT FOR SALE

Date of Manufacture: _____
Date of Expiry: _____
Batch/Lot No.: _____

D. Product Recall & Disposal:

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal);

2. In cases of expired drugs, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Services (AS) of the DOH health facility, subject to compliance to applicable laws.

_____
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]

Technical Specifications

Republic of the Philippines
Department of Health
TECHNICAL SPECIFICATIONS

Item No. 3	**Co-Amoxiclav Suspension**	Quantity / Unit	**5,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 3: **PhP752,700.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. Detailed Technical Specifications: **1. Route of Administration**: Oral **2. Form and Strength**: a) Suspension b) 200 mg amoxicillin (as trihydrate) + 28.5 mg potassium clavulanate per 5mL granules/powder for suspension, 70 mL	

B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1) Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

2) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

   Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 June 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

3) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

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, Certificate or Contract from the manufacturer or importer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 3	**Co-Amoxiclav Suspension**	Quantity / Unit	**5,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 3: **PhP752,700.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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. Contract between the distributor/dealer and the bidder.

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 expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

6) Sworn Statement *using the prescribed form.*

C. <u>Upon delivery the following shall be complied with:</u>

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:**

   Standard packaging of the manufacturer as approved by PFDA.

3. **Labeling instructions:**

   a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.

   b) In addition to the labeling requirements of FDA:

      1. On each bottle, the following shall 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

      2. On each small and bigger box, the following shall be imprinted or stickered with

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 3	**Co-Amoxiclav Suspension**	Quantity / Unit	**5,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 3: **PhP752,700.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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.: _____

D. Product Recall & Disposal:

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal);

2. In cases of expired drugs, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Services (AS) of the DOH health facility, subject to compliance to applicable laws.

_____
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]

Technical Specifications

Republic of the Philippines
Department of Health
TECHNICAL SPECIFICATIONS

Item No. 4	**Cetirizine Tablet**	Quantity / Unit	**300,000 tablets**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 4: **PhP141,000.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. Detailed Technical Specifications: **1. Route of Administration**: Oral **2**. **Form and Strength**: a) Tablet b) 10 mg (as dihydrochloride)	

B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1) Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

2) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

   Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 June 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

3) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

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, Certificate or Contract from the manufacturer or importer 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:

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 4	**Cetirizine Tablet**	Quantity / Unit	**300,000 tablets**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 4: **PhP141,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
ii. Contract between the distributor/dealer and the bidder.

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 expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

6) Sworn Statement *using the prescribed form.*

C. <u>Upon delivery the following shall be complied with:</u>

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:**

Standard packaging of the manufacturer as approved by PFDA.

3. **Labeling instructions:**

a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.
b) In addition to the labeling requirements of FDA:

1. On each blister pack, the following shall 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

2. On each small and bigger box, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 4	**Cetirizine Tablet**	Quantity / Unit	**300,000 tablets**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 4: **PhP141,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
removed: Philippine Government Property – Department of Health **NOT FOR SALE** Date of Manufacture: _____ Date of Expiry: _____ Batch/Lot No.: _____			

D. **Product Recall & Disposal:**

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal);

2. In cases of expired drugs, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Services (AS) of the DOH health facility, subject to compliance to applicable laws.

_____
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 Ad

Technical Specifications

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 5	**Cetirizine Solution**	Quantity / Unit	**5,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 5: **PhP166,200.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. Detailed Technical Specifications: **1. Route of Administration**: Oral **2. Form and Strength**: a) Solution b) 1mg/mL, 60 mL bottle (as dihydrochloride)			

B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1) Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

2) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

   Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 June 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

3) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

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, Certificate or Contract from the manufacturer or importer 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

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 5	**Cetirizine Solution**	Quantity / Unit	**5,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 5: **PhP166,200.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

be provided:

i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
ii. Contract between the distributor/dealer and the bidder.

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 expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

6) Sworn Statement *using the prescribed form.*

C. <u>Upon delivery the following shall be complied with:</u>

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:**

Standard packaging of the manufacturer as approved by PFDA.

3. **Labeling instructions:**

a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.
b) In addition to the labeling requirements of FDA:

1. On each bottle, the following shall 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

2. On each small and bigger box, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed:

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 5	**Cetirizine Solution**	Quantity / Unit	**5,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
ABC for Item No. 5: **PhP166,200.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

Philippine Government Property – Department of Health
NOT FOR SALE

Date of Manufacture: _____
Date of Expiry: _____
Batch/Lot No.: _____

D. Product Recall & Disposal:

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal);

2. In cases of expired drugs, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Services (AS) of the DOH health facility, subject to compliance to applicable laws.

_____
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]

Checklist of Technical and Financial Documents Arranged numbered and tabbed as it appears below:

I. TECHNICAL COMPONENT ENVELOPE

Class "A" Documents

Legal Documents

☐ (a) Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages);

or

☐ (b) Registration certificate from Securities and Exchange Commission (SEC), Department of Trade and Industry (DTI) for sole proprietorship, or Cooperative Development Authority (CDA) for cooperatives or its equivalent document,

and

☐ (c) Mayor's or Business permit issued by the city or municipality where the principal place of business of the prospective bidder is located, or the equivalent document for Exclusive Economic Zones or Areas (together with corresponding copy of receipt(s) of payments of the said permit);

In consideration of the limited access to financial institutions, regulatory and other offices, as well as the implementation of government restrictions on transport and travel, Acceptability of the recently expired Mayor's or Business permits and the Official Receipt as proof that the Bidder has applied and paid for the renewal of the permit ; Provided that, the current and valid Mayor's or Business Permit as renewed, will be submitted by the bidder with the LCRB after the award of contract but before payment (GPPB Circular 09-2020)

and

☐ (d) Tax clearance per E.O. No. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR).

Technical Documents

☐ (e) Statement of the prospective bidder of all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar or not similar in nature and complexity to the contract to be bid; **and**

☐ (f) Statement of the bidder's Single Largest Completed Contract (SLCC) similar to the contract to be bid *equivalent to at least twenty five percent (25%) of the ABC*, except under conditions provided for in Sections 23.4.1.3 and 23.4.2.4 of the 2016 revised IRR of RA No.

9184, within the relevant period as provided in the Bidding Documents; **and**

☐ (g) Original copy of Bid Security. If in the form of a Surety Bond, submit also a certification issued by the Insurance Commission;

or

Original copy of Notarized Bid Securing Declaration; **and**

☐ (h) Conformity with the Schedule of Requirements and Technical Specifications, which may include production/delivery schedule, manpower requirements, and/or after- sales/parts, if applicable; **and**

☐ (i) Original duly signed Omnibus Sworn Statement (OSS);

and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder.

Note: In consideration of the limited access to financial institutions, regulatory and other offices, as well as the implementation of government restrictions on transport and travel, submission of Unnotarized Bid Securing Declaration and Omnibus Sworn Statement are acceptable for procurement activities during a State of Calamity, or implementation of community quarantine or similar restrictions declared or being implemented either in the locality of the PE or of the Bidder, subject to compliance therewith after award of contract but before payment (GPPB Circular 09-2020)

Financial Documents

☐ (j) The Supplier's audited financial statements, showing, among others, the Supplier's total and current assets and liabilities, stamped "received" by the BIR or its duly accredited and authorized institutions, for the preceding calendar year which should not be earlier than two (2) years from the date of bid submission; **and**

☐ (k) The prospective bidder's computation of Net Financial Contracting Capacity (NFCC);

or

A committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation.

☐(l) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already in existence;
or
duly notarized statements from all the potential joint venture partners stating that they will enter into and abide by the provisions of the JVA in the instance that the bid is successful.

Other documentary requirements under RA No. 9184 (as applicable)

☐ (m) *[For foreign bidders claiming by reason of their country's extension of reciprocal rights to Filipinos]* Certification from the relevant government office of their country stating that Filipinos are allowed to participate in government procurement activities for the same item or product.

☐ (n) Certification from the DTI if the Bidder claims preference as a Domestic Bidder or Domestic Entity.

II. FINANCIAL COMPONENT ENVELOPE

☐ (a) Original of duly signed and accomplished Financial Bid Form; **and**

☐ (b) Original of duly signed and accomplished Price Schedule(s).

III. ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN THE TECHNICAL SPECIFICATIONS FORM:

☐ (a) Valid and current Certificate Product Registration (CPR) or Expired CPR with Extension of Validity issued by Philippine Food and Drug Administration (PFDA);

☐ (b) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 June 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

☐ (c) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

☐ (d) 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, Certificate or Contract from the manufacturer or importer 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. Contract between the distributor/dealer and the bidder.

☐ (e) 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 expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

☐ (f) Sworn Statement *using the prescribed form.*

Note:

1) Please refer to ***https://doh.gov.ph/sites/default/files/basic-page/COBAC-Sample-Forms.pdf*** for the following requirements:

a) Sworn Statement;
b) Computation of NFCC;
c) Manufacturer's Authorization;
d) Secretary's Certificate;
e) Special Power of Attorney;
f) Statement of Ongoing Contracts; and
g) Statement of SLCC.

2) For the following requirements, please refer to **GPPB Resolution No. 16-2020:**

   a) Bid Form;
   b) Price Schedule;
   c) Bid Securing Declaration; and
   d) Omnibus Sworn Statement