

INVITATION TO BID

State of Ohio
Department of Administrative Services
General Services Division
Office of Procurement Services

The Original Signed Bid must be submitted to the Office of Procurement Services to receive consideration for award.		BIDDER NAME	
BID NUMBER <u>OT903413</u>	OPENING DATE (1:00 p.m.) <u>DECEMBER 21, 2012</u>	STREET ADDRESS <input type="checkbox"/> Check if remit address is different and list on separate sheet	
General Services Division Office of Procurement Services 4200 Surface Road Columbus, OH 43228-1395 Attn: Bid Desk		CITY	STATE
		ZIP	
		COUNTY	MBE/EDGE CERTIFICATE NUMBER
		TELEPHONE NO. ()	TOLL FREE NO. 1 - ()
REQ./INDEX NO. LDC006		BID NOTICE DATE DECEMBER 4, 2012	CONTACT PERSON
			FAX NO. ()
CONTRACTOR'S E-MAIL ADDRESS			
SELECT YOUR PREFERRED METHOD OF RECEIVING PURCHASE ORDERS AND ENTER THE E-MAIL OR FAX NUMBER INFORMATION (ONLY SELECT ONE METHOD) <input type="checkbox"/> E-Mail <input type="checkbox"/> Fax			
In addition to the standard terms for payment, the payment terms for state agency(ies) will be 2%, 10 Days, Net 30 Days unless otherwise stated in the following space. If no discount is offered, bidder should circle "Net 30 Days". _____%, _____Days, Net 30 Days			
PARTICIPATING AGENCY(IES): OHIO DEPARTMENT OF MENTAL HEALTH, OFFICE OF SUPPORT SERVICES, 2150 WEST BROAD STREET, COLUMBUS, OHIO 43223, AND THE OHIO DEPARTMENT OF HEALTH, 900 FREEWAY DRIVE NORTH, BLDG. 8, COLUMBUS, OHIO 43229.			
THE DEPARTMENT OF ADMINISTRATIVE SERVICES, OFFICE OF PROCUREMENT SERVICES, IS SOLICITING BIDS FOR: INFLUENZA VACCINE 2013-2014			
TERM OF CONTRACT: This Invitation to Bid is to establish a requirements contract to procure the described supplies or services on behalf of the above participating agency(ies). The agency(ies) may place orders against the Contract beginning <u>01/15/13</u> or upon the date when DAS signs the Contract, whichever is later in time. The Contract will expire <u>12/31/13</u> unless DAS terminates the Contract based upon reasons set forth in Article I-C of the Standard Contract Terms and Conditions. No agencies may place purchase orders against the Contract beyond the expiration date unless DAS renews the Contract by amendment. The Contractor may begin performance under the Contract only upon receipt of a valid order from a participating state agency.			
INSTRUCTIONS TO BIDDERS AND CONTRACT TERMS AND CONDITIONS, Revised 09/2012, are a part of this Invitation to Bid. Copies may be downloaded by clicking on this link: Instructions: Terms and Conditions for Bidding, Standard Contract Terms and Conditions, and Supplemental Contract Terms and Conditions. All prior versions of Instructions to Bidders, Contract Terms and Conditions are null and void.			
By submitting this Invitation to Bid, the Contractor certifies that Contractor has truthfully disclosed the location(s) where all services are to be performed; the location(s) where all applicable State contract data is to be maintained or made available; and the principal location of business for the Contractor and all subcontractors. The Contractor further certifies and acknowledges that Contractor will not change the country of the location(s) where services are performed and will not change the country of the location(s) where data is maintained or made available without prior written consent of the State.			
Any questions or clarifications regarding this Invitation to Bid should be directed to the Office of Procurement Services through the Internet at www.procure.ohio.gov/ . All questions should be submitted a minimum of four (4) working days prior to the bid opening date.			
PRINTED/TYPED SIGNATURE		AUTHORIZED SIGNATURE (ORIGINAL SIGNATURE ONLY) (Please sign in blue ink)	DATE

The ORIGINAL signed Bid must be submitted to the Office of Procurement Services by 1:00 o'clock p.m., on the above listed opening date to receive consideration for award. It is requested that the Bidder NOT sign their bid in BLACK ink. BIDDER CERTIFIES, by signature affixed to its bid, that the information provided by it in its bid including the certified statements, is accurate and complete. Bidder declares to have read and understood and agrees to be bound by all of the instructions, terms, conditions and specifications of this Invitation to Bid and agrees to fulfill the requirements of any awarded contract at the prices bid.

REQUIRED CERTIFICATION FOR BIDDING

Those bidders claiming preference for Domestic Source End Products and/or the Ohio preference, pursuant to Revised Code Sections 125.09 and 125.11 and Administrative Code Section 123:5-1-06 must complete the following information. Bidders who qualify as an "Ohio" bidder (offer an Ohio product or who have significant Ohio economic presence) or who qualify as a Border State bidder are eligible to receive a five percent (5%) preference over non-Ohio/Border state bidders. The state reserves the right to clarify any information during the evaluation process. **BIDDERS MUST COMPLETE THIS CERTIFICATION TO RECEIVE THE PREFERENCE.**

A. DOMESTIC PREFERENCE (BUY AMERICA): [Not applicable to "Excepted Products"]

- Where is each product/services being offered mined, raised, grown, produced or manufactured?
 United States: _____(State) Canada Mexico (Go to B-1)
 Other: (Specify Country) _____ (Go to A-2)
- End product is manufactured outside the United States and at least 50% of the cost of its components are produced, mined, raised, grown or manufactured within the United States. The cost of components may include transportation costs to the place of manufacture and, in the case of components of foreign origin, duty whether or not a duty free entry certificate is issued.
 Yes (Go to Section B-1) No (Go to Section A-3)
- The Bidder hereby certifies that each end product, except the products listed below, is a domestic source end product as defined in the Buy America Act and that components of unknown origin have been considered to have been mined, produced, grown or manufactured outside the United States.

_____ (Item) _____ (Country) of
Origin)

_____ (Item) _____ (Country) of
Origin)

A domestic end source product is deemed to be excessively priced if it exceeds the cost of the foreign product by more than 6%. Pursuant to FAR, Part 25, the state of Ohio does not acquire supplies or services that cannot be imported lawfully into the United States. The contractor, their subcontractor(s) and any agent of the contractor or subcontractor must not acquire any supplies or services originating from sources within, or that were located in or transported from or through Cuba, Iran, Iraq, Libya, North Korea, Sudan Territory of Afghanistan controlled by the Taliban, or Serbia (excluding the territory of Kosovo).



B. OHIO PREFERENCE (BUY OHIO):

- The products/services being offered are raised, grown, produced, mined or manufactured in Ohio.
 Yes (Go to C) No (Go to B-2)
- Bidder has significant economic presence within the state of Ohio.
 Yes (Answer a, b, c, d below) No (Go to B-3)
 - Bidder has paid the required taxes due the state of Ohio Yes No
 - Bidder is registered with the Ohio Secretary of State
 Yes (Charter/Registration No.: _____) No
Questions regarding registration should be directed to (614) 466-3910 or visit their web site at:
<http://www.sos.state.oh.us/>
 - Bidder has ten or more employees based in Ohio or border state. Yes No (Go to B-2d)
 - Bidder has seventy-five percent or more employees based in Ohio or border state.
 Yes No (Go to B-3)
- Border state bidder:
 Yes (Specify which state then go to B-2c): KY MI NY PA IN No (Go to B-4)
- Border state bidder: mined products mined in respective border state Yes No Not Applicable

C. E.D.G.E. DESIGNATION

Bidder is certified E.D.G.E. business Yes No

For information on E.D.G.E. designation, please visit the DAS Equal Opportunity Division website at:
<http://www.das.ohio.gov/Divisions/EqualOpportunity/tabid/80/Default.aspx>

AMENDMENTS TO CONTRACT TERMS AND CONDITIONS

AMENDMENTS TO CONTRACT TERMS AND CONDITIONS: The following Amendments to the Contract Terms and Conditions do hereby become a part hereof. In the event that an amendment conflicts with the Contract Terms and Conditions, the Amendment will prevail.

DESCRIPTIVE LITERATURE: The Bidder may be required to submit descriptive literature of the supplies or services being offered. If requested, the literature will be used in the evaluation process to determine the lowest responsive and responsible bidder. If not provided as part of the bid response, the Bidder must provide said literature within ten (10) calendar days after request/notification by the Office of Procurement Services to do so. Any references, that may appear in the descriptive literature, that may alter the terms and conditions and specifications of the bid (e.g. F.O.B. Shipping Point or Prices Subject to Change), will not be part of any contract and will be disregarded by the state of Ohio. Failure of the bidder to furnish descriptive literature either as part of their bid response or within the time specified herein will deem the bidder not responsive.

DELIVERY AND ACCEPTANCE: Vendor shall acknowledge all purchase orders within seven (7) calendar days after receipt. All merchandise shall be shipped in accordance with required delivery/receipt dates as specifically stated in the purchase order and for store door delivery. Supplies will be delivered to the participating agency, in accordance with paragraphs S-8, S-9, and S-10 of the SUPPLEMENTAL CONTRACT TERMS AND CONDITIONS. Any item(s) ordered from a contract awarded pursuant to this bid shall be shipped F.O.B. destination, freight prepaid. Shipment shall be made to Ohio Department of Mental Health, Office of Support Services, 2150 West Broad Street, Columbus, Ohio 43223 and to the Ohio Department of Health, 900 Freeway Drive North, Bldg. 8, Columbus, Ohio 43229, unless otherwise indicated herein. Delivery quantities and dates may be adjusted by mutual agreement between the Agency and Contractor. Acceptance (transfer of title) will occur upon the inspection and written confirmation by the ordering agency that the supplies delivered conform to the requirements set forth in the Contract. Unless otherwise provided in the Contract, acceptance shall be conclusive except as regards to latent defects, fraud, or such gross mistakes as amount to fraud.

For Item Numbers 210-80-1359V-DS and 210-80-1360V-DS, the following exceptions to the above Delivery and Acceptance terms and conditions shall apply: As indicated on the purchase order issued by the Ohio Department of Health (ODH), supplies may be delivered to among approximately 250 dispensing provider office locations within the state of Ohio. In addition, for Item No. 210-80-1359V-WL, as indicated on the purchase order issued by the Ohio Department of Health (ODH), supplies may be delivered to a third party distributor's warehouse location. Delivery quantities, dates, and locations may be adjusted by mutual agreement between the ODH and Contractor. The ODH shall reserve the right to adjust the delivery location of the purchase order before shipment occurs. Acceptance (transfer of title) will occur upon the inspection and written confirmation by the receiving dispensing provider or third party distributor, or the ODH, that the supplies delivered conform to the requirements set forth in the Contract. Unless otherwise provided in the Contract, acceptance shall be conclusive except as regards to latent defects, fraud, or such gross mistakes as amount to fraud.

EVALUATION: Bids will be evaluated in accordance with Article I-17 of the "Instructions to Bidders". In addition, the State will multiply the unit cost by the estimated usage (estimated yearly requirements) specified in the bid for each line item to arrive at a total for each line item. If the estimated usage is unknown, then one (1) will be used as the estimated usage, for calculation purposes only.

CONTRACT AWARD: The contract will be awarded to the lowest responsive and responsible bidder by line item, meeting all bid specifications and requirements listed herein.

FIRM FIXED-PRICE CONTRACT: The contract is a Firm Fixed-Price Contract. The Contractor(s) is required to provide to the using agency supplies or services at the listed price(s) for the duration of the contract, and any extensions thereto.

USAGE REPORTS: Every six (6) months the contractor must submit a report (written or on disk) indicating sales generated by this contract. The report shall list usage by customer, by line item, showing the quantities/dollars generated by this contract. The report shall be forwarded to the Office of Procurement Services, 4200 Surface Road, Columbus, OH 43228-1395, Attn: Terry Spiropoulos.

AMENDMENTS TO CONTRACT TERMS AND CONDITIONS (Cont'd.)

MINIMUM ORDER: No order shall be placed against a contract awarded pursuant to this bid for less than twenty-five (\$25.00) dollars. The minimum dollar value any of order placed against a contract awarded pursuant to this bid for delivery F.O.B. destination, transportation charges prepaid, at any one time to one destination, shall not be less than three hundred (\$300.00) dollars.

OHIO LICENSE: All bidders must hold a current Ohio Wholesale Distributor of Dangerous Drug License if the products offered are dangerous (legend) drugs. Failure to list a current Ohio Wholesale Distributor of Dangerous Drug License on Page 9 indicates that the bidder is not appropriately licensed to sell dangerous drugs in the state of Ohio and will result in the bidder being deemed as not responsive.

AUTHORIZED WHOLESALER/DISTRIBUTOR: Bids will be accepted only from established manufacturers and/or their authorized wholesalers/distributors. Any wholesaler/distributor submitting a bid hereby acknowledges that they are an authorized wholesaler/distributor of the manufacturers quoted and that the manufacturer has agreed to supply the wholesaler/distributor with all quantities of the items required by the wholesaler/distributor in fulfillment of its obligations under any resultant contract with the state of Ohio.

The Office of Procurement Services reserves the right to request agreement documentation confirming a contractor's distributor/wholesaler relationship with quoted manufacturers. When notified, the bidder will be required to provide the copies of said agreements, for any manufacturers requested by the Office of Procurement Services, within five (5) business days after notification, to the Office of Procurement Services. Failure to provide the agreements within the stated time period may result in the bidder being deemed as not responsive.

SPECIAL CONDITIONS: The Director, Department of Administrative Services (DAS), reserves the right to bid large or unusual requirements, for items that may be a part of the awarded contract, under a separate bid. The State may elect to participate in any Centers for Disease Control (CDC) contract that may be available to the Ohio Department of Health, 900 Freeway Drive North, Bldg. 8, Columbus, Ohio 43229.

PLACEMENT OF ORDERS: Purchase orders for any item(s) listed in a contract awarded pursuant to this bid will be placed directly with the successful contractor(s) by the using agency. No order shall specify delivery to exceed thirty (30) days beyond the expiration and/or cancellation date of the contract.

RETURN GOODS: All bidders are requested to submit their company's policy on Returned Goods with their bid.

BID AUTOMOBILE LIABILITY CHECKLIST:

Contractor will indicate, by checking the appropriate box(es) below, which mode of transportation will apply to this contract.

- Bidder/Broker ("The Contractor") or their Sub Contractor will make delivery or be performing services using a vehicle that is owned, leased or rented. Provide Certificate of Insurance documenting automobile liability with a Combined Single Limit of \$500,000.00
- Goods/Services will be delivered via common carrier.
- No employee or representative of the contractor will have cause to be on state property to make deliveries or to perform services.

AMENDMENTS TO CONTRACT TERMS AND CONDITIONS (Cont'd.)

DISCLOSURE OF SUBCONTRACTORS / JOINT VENTURES (See Standard Contract Terms and Conditions, Section (roman numeral) V. General Provisions, Paragraph Q.):

List names of subcontractors who will be performing work under the Contract.

_____	_____
_____	_____
_____	_____

By the signature affixed to Page 1 of this Bid, Bidder hereby certifies that the above information is true and accurate. The Bidder agrees that no changes will be made to this list of subcontractors or locations where work will be performed or data will be stored without prior written approval of DAS. Any attempt by the Bidder/Contractor to change or otherwise alter subcontractors or locations where work will be performed or locations where data will be stored, without prior written approval of DAS, will be deemed as a default. If a default should occur, DAS will seek all legal remedies as set forth in the Terms and Conditions which may include immediate cancellation of the Contract. Failure to complete this page may deem your bid not responsive.

NOTICE ON THE USE OF SOCIAL SECURITY NUMBERS AS FEDERAL TAX IDENTIFICATION NUMBERS:

The Department of Administrative Services (Department) requires vendors and contractors wishing to do business with the State to provide their Federal Taxpayer Identification Number to the Department. The Department does this so that it can perform statutorily required "responsibility" analyses on those vendors and contractors doing business with the State and, under limited circumstances, for tax reporting purposes. If you are a vendor or contractor using your Social Security Number as your Federal Taxpayer Identification Number, please be aware that the information you submit is a public record, and the Department may be compelled by Ohio law to release Federal Taxpayer Identification Numbers as a public record. If you do not want to have your Social Security Number potentially disclosed as a Federal Taxpayer Identification Number, the Department encourages you to use a separate Employer Identification Number (EIN) obtained from the United States Internal Revenue Service's to serve as your Federal Taxpayer Identification Number.

SPECIFICATIONS

I. SCOPE AND CLASSIFICATION:

- A. Scope: The State of Ohio, Department of Administrative Services, Office of Procurement Services, on behalf of the Ohio Department of Health and the Ohio Department of Mental Health, is seeking bids for Influenza Vaccines, 2013-2014 year (influenza season). Products shall be delivered FOB destination, prepaid, as specified in the paragraph, "Delivery and Acceptance." This procurement of Influenza Virus Vaccine shall be compliant with the specifications and requirements listed herein. The term of any contract issued pursuant to this ITB shall be approximately eleven (11) months from January 15, 2013 through December 31, 2013.
- B. Classification
1. Influenza Virus Vaccine, Inactivated, Trivalent Split, to include the Antigens as formulated in accordance with the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year. This type is also known as TIV.
 2. Influenza Virus Vaccine Live Attenuated, Intranasal Spray, to include the Antigens as formulated in accordance with the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year. This type is also known as LAIV.

II. APPLICABLE DOCUMENTS

- A. Applicable section(s) of Food, Drug, and Cosmetic Act
- B. Applicable section(s) of the Code of Federal Regulations, Title 21
- C. Applicable section(s) of the Ohio Pure Food, Drug, and Cosmetic Law, ORC Chapter 3715
- D. Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), FDA Publication

III. REQUIREMENTS

- A. Products
1. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Formulation, licensed for administration to ages 6 months and over, to include the Antigens as formulated in accordance with the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials.
Item Number #210-80-1359V.
 2. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult No Preservative Formulation, licensed for administration to ages 36 months and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes (packaged in boxes of 10 Pre-Filled Syringes / box).
Item Number #210-80-1359S.

SPECIFICATIONS ((Cont'd.))

3. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult No Preservative Formulation, licensed for administration to ages 18 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes (packaged in boxes of 5 or 10 Pre-Filled Syringes / box).
Item Number #210-80-1360S.
4. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Formulation, licensed for administration to ages 18 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials.
Item Number #210-80-1360V.
5. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Formulation, licensed for administration to ages 4 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials.
Item Number #210-80-1361V.
6. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Preservative Free Formulation, licensed for administration to ages 4 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes (packaged in boxes of 10 Pre-Filled Syringes / box).
Item Number #210-80-1361S.
7. Influenza Virus Vaccine, Inactivated, Trivalent Split, Pediatric No Preservative Formulation, licensed for administration to ages 6 – 35 months, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.25 ml Pre-Filled Syringes (packaged in boxes of 10 Pre-Filled Syringes / box).
Item Number #210-80-1359.
8. Influenza Virus Vaccine, Live Attenuated, Intranasal Spray, licensed for administration to ages 2-49 years, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Use, 0.2 ml Sprays (packaged in boxes of 10 Single-Use Sprays / box).
Item Number #210-80-1361.
9. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Formulation, licensed for administration to ages 6 months and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials. Directly shipped to dispensing provider offices within Ohio.
Item Number #210-80-1359V-DS.

SPECIFICATIONS ((Cont'd.))

10. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Formulation, licensed for administration to ages 18 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials. Directly shipped to dispensing provider offices within Ohio.
Item Number #210-80-1360V-DS.
 11. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult High-Dose Preservative Free Formulation, licensed for administration to ages 65 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes (packaged in boxes of 10, or less, Pre-Filled Syringes / box). (Example: Sanofi Pasteur Fluzone High-Dose, or equivalent).
Item Number #210-80-1358S.
 12. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Intradermal Preservative Free Formulation, licensed for administration to ages 18-64 years, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.1 ml Pre-Filled Syringes (packaged in boxes of 10, or less, Pre-Filled Syringes / box). (Example: Sanofi Pasteur Fluzone Intradermal, or equivalent) Note: This utilizes a very small needle, not a jet injector.
Item Number #210-80-1357S.
 13. Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Formulation, licensed for administration to ages 6 months and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials. Directly shipped to a third party distributor's warehouse location, as specified by Dept. of Health, and likely should be located in the eastern United States.
Item Number #210-80-1359V-WL.
- B. Use: All types of pharmaceuticals and chemicals, as listed herein, shall be suitable for human medicinal use.
- C. Compliance: Manufacturing firms of the supplied items shall adhere to the most updated regulations under the Federal Food, Drug, and Cosmetic Act, embodied in "Drugs: Current Good Manufacturing Practice in manufacture, processing, packaging, or holding"; and Part 210 and 211, Title 21 Code of Federal Regulations, Food and Drugs.
- For all items, with FDA required 'New Drug Applications' or 'Abbreviated New Drug Applications', manufacturers shall hold an NDA or ANDA, which shall be in effect at the time of the bid. Bidders may be required to submit a copy of the NDA or ANDA approval letter or approval number and date of approval before or during the contract award.
- D. Change of Source(s): The successful bidder(s) shall not change, unless approved by the State in writing, the manufacturing source(s) from which they specified in their bid. Failure to comply with this requirement may subject the resulted contract to cancellation, in addition to other applicable remedies.

SPECIFICATIONS ((Cont'd.))

- E. Special Charges: There shall be no assessment, surcharge, small order charge, broken case charge, minimum order charge, single item charge nor any other unspecified additional charge allowed by the State that is not specifically mentioned in this bid or in any contract awarded pursuant to this bid. The contractor must provide merchandise/service in unit quantity(s) as indicated in the bid/bid response/contract.
- F. Return Goods: All bidders are requested to submit their company's policy on Returned Goods with their bid.

IV. CONTRACTOR QUALIFICATIONS

- A. Authorized Distributor: If the bidder is not the manufacturer of the product offered, the bid response should include a letter from the manufacturer, on manufacturer's letterhead, that the bidder is authorized to represent the manufacturer in this bid effort. The letter must guarantee that all requirements of this bid will be supported by the manufacturer to include, at least as a minimum: delivery of product within the specified time frame, proper handling and quality of product delivered, and compliance with all bid specifications.
- B. Ohio License: All bidders must hold a current Ohio Wholesale Distributor of Dangerous Drug License if the products offered are dangerous (legend) drugs. Enter your Ohio Wholesale Distributor of Dangerous Drugs License Number and Expiration Date below and attach a copy of your Ohio license to this page. For more information contact the Ohio State Board of Pharmacy at (614) 466-4143.

Failure to accurately complete this section indicates that the bidder is not appropriately licensed to sell dangerous drugs in the state of Ohio and will result in the bidder being deemed as not responsive.

Please state your Ohio license number: _____

License number expiration date: _____

(Staple a copy of your current Ohio Wholesale Distributor of Dangerous Drug License here.)

SPECIFICATIONS (Cont'd.)

C. Notarized Form: This page shall be completed and notarized with original notarial seal and signatures. Each bidder is requested to provide the following information with the bid proposal.

PURCHASE ORDERS AGAINST THIS BID
SHALL BE MAILED TO:

REMITTANCE ADDRESS AGAINST THIS BID
SHALL BE MAILED TO:

FIRM NAME

FIRM NAME

STREET ADDRESS

STREET ADDRESS

CITY & STATE ZIP CODE

CITY & STATE ZIP CODE

CERTIFICATE: Each bidder shall be required to execute the following notarized certificate covering the bid for those items which Bidder proposes to furnish. Failure to execute the certificate will result in the Bidder being deemed as not responsive.

All ingredients used in the preparation of all drugs, chemicals and pharmaceuticals for which we have rendered bids against this bid/contract are tested regularly by chemical assay, biologically and/or physiologically as required. All ingredients comply with U.S.P. requirements or better. All finished products are assayed chemically, biologically and physiologically as required and meet standards or other applicable standards for identity, strength, quality and purity, including potency and where applicable, content uniformity, disintegration times or dissolution rates. All injectable materials are checked for sterility as required. Our standards meet all the minimum requirements of any applicable regulations of the National Institute of Health or the Food and Drug Administration.

A complete record of control is kept covering our test records of all ingredients as received and all products as manufactured and also a record of chemical, biological, physiological and sterility assays of all finished products with a reference file of samples from the batches tested.

Manufacturer or Bidder

By: _____

Title: _____

Date: _____

State of _____

County of _____

On this ____ day of _____, _____ before me a notary public, in authority of his office under the by-laws of the above corporation, stated the above certificate is true and correct.

In witness whereof, I have hereunto subscribed my name and affixed my official seal.

Notary Public

THE ABOVE FORM MUST BE COMPLETED AND SIGNED AND NOTARIZED

SPECIFICATIONS (Cont'd.)

V. DOCUMENTATION:

A. MANDATORY WITH BID RESPONSE

1. Page 1 with original, authorized signature and requested information entered.
2. Pages 13 through 18 of the ITB with all requested information entered. Item Price Page(s) are not required to be submitted if blank, with no bid offer for any item(s) on the page.
3. To receive Ohio preference, Page 2 must be completed and submitted with the bid response.

Failure to submit the above documents, with the exception of page 2 and any blank Item Price Pages, will deem the bid not responsive and no further consideration for award will be given.

B. REQUESTED WITH BID RESPONSE

1. The address form and Notarized Certificate on Page 10
2. Bidders responding to this ITB must be authorized dealers or manufacturers of the products they are bidding. Bidders should submit, with the ITB submittal, certification attesting that they are the manufacturer or an authorized dealer of the manufacturer of the products being bid. This certification must be on the manufacturer's letterhead, signed by a duly authorized manufacturer's representative.
3. Descriptive literature or manufacturer's specification sheets or correct NDC numbers, describing each item being offered, should be submitted with the ITB submittal. Specification sheets should be labeled with the name of the manufacturer, the NDC number, description, indications, and the number of the item bid corresponding to the line item of the item on the Item Price Pages 13 through 18 of this ITB.
4. Copy of completed Internal Revenue Service (IRS) form W-9, indicating the Taxpayer Identification Number (TIN). A web address to obtain the form is at: <http://www.irs.gov/formspubs/index.html>
If additional assistance is needed in completing the W-9 form, you may contact the IRS at 1-800-829-1040.
5. Certificate of Insurance and copy of current Workers' Compensation Certificate (see Supplemental Contract Terms and Conditions, paragraphs S-12 and S-13)
6. Returned Good Policy: All bidders are requested to submit their company's policy on Returned Goods with their bid
7. Affirmative Action Program Verification letter of approval. In accordance with a requirement set forth in the Ohio Revised Code (ORC Section 125.111), bidders must complete filing of an Affirmative Action Plan to the Department of Administrative Services (DAS), Equal Opportunity Division (EOD) prior to award of a contract.

Affirmative Action Program Registration letter of approval: The Affirmative Action Program Verification Form may be renewed or completed and filed online by starting the following web address:
<http://das.ohio.gov/Divisions/EqualOpportunity/AffirmativeActionProgramVerification.aspx>

After the registration process, a copy of the letter of approval may be obtained at the following web address:
<http://eodreporting.oit.ohio.gov/searchAffirmativeAction.aspx>

Search by entering the company name or TIN, click on the name, and a printable copy of the letter of approval should appear. This letter shows verification of filing of Affirmative Action Plan.

You may call the EOD office at 614-466-8380 to inquire, if needed.

SPECIFICATIONS (Cont'd.)

8. Bid Automobile Liability Checklist (see Page 4 of the Invitation to Bid).
9. Disclosure of Subcontractors / Joint Ventures (see Page 5 of the Invitation to Bid).
10. Copy of Bidder's Ohio Wholesaler Distributor of Dangerous Drug License (see Page 9).
11. Registration with the Ohio Secretary of State, Charter/Registration Number. In accordance with the Standard Contract Terms and Conditions, Article I-29, bidder should be registered with the Ohio Secretary of State, as applicable. Bidder may provide this number on Page 2 of the bid, or in a separate document such as a printout obtained through the following Web site. The Charter/Registration Number may be verified by searching through Business Filings in the main SOS Web site at: <http://www.sos.state.oh.us>

If documents listed in paragraphs B.1 through B.11 above are not submitted with the bid response, they may be requested during the bid evaluation. If requested during the bid evaluation, documents must be received within seven (7) calendar days of verbal or written request. Failure to provide requested documents by the deadline provided during evaluation will deem your bid not responsive and no further consideration for award will be provided.

VI. BID PRICE AND PRODUCT OFFER:

- A. BID UNIT PRICE: Bid prices in the Item Price Page(s) will be per dose. Although the Unit Quantity/package size may vary among items, all bid prices offered by the Bidder shall be for one (1) dose including Federal Excise Tax (FET). The purpose for this is to simplify bidding and to eliminate pricing errors. Any contract resulting from this ITB will reflect the correct unit quantity size(s) and corresponding pricing.
- B. ITEM PRICE PAGES: The following pages will contain the Item Price Pages. Bidder shall indicate on the Item Price Pages, all of the items (products) it is offering in its Bid submission by indicating the Item Offered, Manufacturer Name and Plant Location, Unit (if applicable), N.D.C. Number, and Price Per Dose, including Federal Excise Tax for each item bid in the columns so labeled. Only prices entered in the Item Price Pages shall be valid, and shall be complete including Federal Excise Tax, and no other prices, attachments, or charges will be considered.

YOUR BID:

Bidder shall not insert a unit cost more than 3 digits after the decimal point. Digit(s) beyond 3, after the decimal point, shall be dropped by the State, DAS Office of Procurement Services, and not used in the evaluation and any subsequent award.

ITEM PRICE PAGES

ITEM I.D. NO. REFERENCE NO.	ITEM REQUESTED	ITEM OFFERED	MANUFACTURER NAME AND PLANT LOCATION	UNIT SIZE	UNIT QTY.	EST. YEARLY REQ.	N.D.C. NUMBER	(Including FET) PRICE PER DOSE
12915 210-80-1359V	Influenza Virus Vaccine, Trivalent Split, Adult Formulation, licensed for administration to ages 6 months and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			<u>10 Dose</u> 5 ml	Each Vial	** * Unknown		\$
12924 210-80-1359S	Influenza Virus Vaccine, Trivalent Split, Adult No Preservative Formulation, licensed for administration to ages 36 months and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			<u>Single Dose</u> 0.5 ml	10 Syr./ Box	** * Unknown		\$

* One (1) will be used as the estimated usage, for calculation purposes.

** The combined total estimated usage quantity is 22,000 doses, among the following line item Reference Numbers: 210-80-1359V, 210-80-1359S, 210-80-1360S, 210-80-1360V, 210-80-1361V, and 210-80-1361S. Awarded contract prices may strongly affect the actual usage distribution.

ITEM PRICE PAGES (Cont'd.)

ITEM I.D. NO. REFERENCE NO.	ITEM REQUESTED	ITEM OFFERED	MANUFACTURER NAME AND PLANT LOCATION	UNIT SIZE	UNIT QTY.	EST. YEARLY REQ.	N.D.C. NUMBER	(Including FET) PRICE PER DOSE
12925 210-80-1360S	Influenza Virus Vaccine, Trivalent Split, Adult No Preservative Formulation, licensed for administration to ages 18 years and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			Single Dose 0.5 ml	Fill-In: Syr./ Box	** *		\$
1693 210-80-1360V	Influenza Virus Vaccine, Trivalent Split, Adult Formulation, licensed for administration to ages 18 years and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			10 Dose 5 ml	Each Vial	** *		\$
12927 210-80-1361V	Influenza Virus Vaccine, Trivalent Split, Adult Formulation, licensed for administration to ages 4 years and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			10 Dose 5 ml	Each Vial	** *		\$

* One (1) will be used as the estimated usage, for calculation purposes.

** The combined total estimated usage quantity is 22,000 doses, among the following line item Reference Numbers: 210-80-1359V, 210-80-1359S, 210-80-1360S, 210-80-1360V, 210-80-1361V, and 210-80-1361S. Awarded contract prices may strongly affect the actual usage distribution.

ITEM PRICE PAGES (Cont'd.)

ITEM I.D. NO. REFERENCE NO.	ITEM REQUESTED	ITEM OFFERED	MANUFACTURER NAME AND PLANT LOCATION	UNIT SIZE	UNIT QTY.	EST. YEARLY REQ.	N.D.C. NUMBER	(Including FET) PRICE PER DOSE
6696 210-80-1361S	Influenza Virus Vaccine, Trivalent Split, Adult Preservative Free Formulation, licensed for administration to ages 4 years and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			Single Dose 0.5 ml	10 Syr./ Box	** 22,000 Doses		\$
1694 210-80-1359	Influenza Virus Vaccine, Trivalent Split, Pediatric No Preservative Formulation, licensed for administration to ages 6 – 35 months, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			Single Dose 0.25 ml	10 Syr./ Box	* Unknown		\$
12926 210-80-1361	Influenza Virus Vaccine Live, Intranasal Spray, licensed for administration to ages 2-49 years, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET).			Single Use Spray 0.2 ml	10 Sprays / Box	(50 Doses) 5 Boxes		\$

* One (1) will be used as the estimated usage, for calculation purposes.

** The combined total estimated usage quantity is 22,000 doses, among the following line item Reference Numbers: 210-80-1359V, 210-80-1359S, 210-80-1360S, 210-80-1360V, 210-80-1361V, and 210-80-1361S. Awarded contract prices may strongly affect the actual usage distribution.

ITEM PRICE PAGES (Cont'd.)

ITEM I.D. NO.	ITEM REQUESTED	ITEM OFFERED	MANUFACTURER NAME AND PLANT LOCATION	UNIT SIZE	UNIT QTY.	EST. YEARLY REQ.	N.D.C. NUMBER	(Including FET) PRICE PER DOSE
15817	Influenza Virus Vaccine, Trivalent Split, Adult Formulation, licensed for administration to ages 6 months and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), directly shipped to dispensing provider offices within Ohio.					(10,000 Doses)		
210-80-1359V-DS				<u>10 Dose</u> 5 ml	Each Vial	1,000 Vials		\$
17901	Influenza Virus Vaccine, Trivalent Split, Adult Formulation, licensed for administration to ages 18 years and over, to include the Antigens as formulated in accordance with the CDC, prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), directly shipped to dispensing provider offices within Ohio.					*		
210-80-1360V-DS				<u>10 Dose</u> 5 ml	Each Vial	Unknown		\$

* One (1) will be used as the estimated usage, for calculation purposes.

ITEM PRICE PAGES (Cont'd.)

ITEM I.D. NO. REFERENCE NO.	ITEM REQUESTED	ITEM OFFERED	MANUFACTURER NAME AND PLANT LOCATION	UNIT SIZE	UNIT QTY.	EST. YEARLY REQ.	N.D.C. NUMBER	(Including FET) PRICE PER DOSE
17902 210-80-1358S	Influenza Virus Vaccine, Trivalent Split, Adult High-Dose Preservative Free Formulation, licensed for administration to ages 65 years and over, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET). (Example: Sanofi Pasteur Fluzone High-Dose, or equivalent).			Single Dose 0.5 ml	Fill-In: _____	20 Doses		\$
21043 210-80-1357S	Influenza Virus Vaccine, Inactivated, Trivalent Split, Adult Intradermal Preservative Free Formulation, licensed for administration to ages 18-64 years, to include the Antigens as formulated in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC), prevention and control of Influenza, recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2013-2014 year, including Federal Excise Tax (FET), in Single-Dose, 0.1 ml Pre-Filled Syringes (packaged in boxes of 10, or less, Pre-Filled Syringes / box). (Example: Sanofi Pasteur Fluzone Intradermal, or equivalent). Note: This utilizes a very small needle, not a jet injector.			Single Dose 0.1 ml	Fill-In: _____	*		\$

* One (1) will be used as the estimated usage, for calculation purposes.

