

STATE OF OHIO
DEPARTMENT OF ADMINISTRATIVE SERVICES
GENERAL SERVICES DIVISION
OFFICE OF PROCUREMENT SERVICES
4200 SURFACE ROAD, COLUMBUS, OH 43228-1395

MANDATORY USE CONTRACT FOR: INFLUENZA VACCINE 2016-2017

CONTRACT No.: OT00908358

EFFECTIVE DATES: 03/01/16 to 02/28/17

The Department of Administrative Services has accepted bids submitted in response to Invitation to Bid No. OT00908358 that opened on 01/15/16. The evaluation of the bid response(s) has been completed. The bidder(s) listed herein have been determined to be the lowest responsive and responsible bidder(s) and have been awarded a contract for the items(s) listed. The respective bid response, including [the Terms and Conditions for Bidding, Standard Contract Terms and Conditions, and Supplemental Contract Terms and Conditions](#), special contract terms & conditions, any bid addenda, specifications, pricing schedules and any attachments incorporated by reference and accepted by DAS become a part of this Requirements Contract.

This Requirements Contract is effective beginning and ending on the dates noted above unless, prior to the expiration date, the Contract is renewed, terminated or cancelled in accordance with the Contract Terms and Conditions.

This Requirements Contract is available to OHIO DEPARTMENT OF MENTAL HEALTH AND ADDICTION SERVICES, OFFICE OF SUPPORT SERVICES, AND THE OHIO DEPARTMENT OF HEALTH., as applicable.

Agencies are eligible to make purchases of the listed supplies and/or services in any amount and at any time as determined by the agency. The State makes no representation or guarantee that agencies will purchase the volume of supplies and/or services as advertised in the Invitation to Bid.

SPECIAL NOTE: State agencies may make purchases under this Requirements Contract up to \$2500.00 using the State of Ohio payment card. Any purchase that exceeds \$2500.00 will be made using the official State of Ohio purchase order (ADM-0523). Any non-state agency, institution of higher education or Cooperative Purchasing member will use forms applicable to their respective agency.

Questions regarding this and/or the Requirements Contract may be directed to:

Ryan Beers, CPPB
ryan.beers@das.ohio.gov

This Requirements Contract and any Amendments thereto are available from the DAS Web site at the following address:

<http://www.ohio.gov/procure>

Signed: _____
Robert Blair, Director Date

TABLE OF CONTENTS

<u>CLAUSES</u>	<u>PAGE NO.</u>
Special Terms and Conditions	3-4
Amendments to Contract Terms and Conditions	3
Descriptive Literature	3
Delivery and Acceptance	3
Evaluation	3
Contract Award	3
Firm Fixed-Price Contract	3
Usage Reports	3
Ohio License	3
Authorized Wholesaler/Distributor	3
Return Goods	4
Bid Automobile Liability Checklist	4
Disclosure of Subcontractors/Joint Ventures	4
Specifications	5-8
Scope and Classification	5
Applicable Documents	5
Requirements	6-8
Item Price Pages	9-13
Contractor Index Page	14

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: Subsequent to award of the contract, the Contractor shall furnish any participating agency with the exact descriptive literature. Requested literature must be provided to the requesting agency within seven (7) calendar days of the request. Failure to provide the descriptive literature to any participating agency as stipulated herein will be considered as an event of default. 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.

DELIVERY AND ACCEPTANCE: Contractor shall acknowledge all purchase orders within forty-eight (48) hours after receipt. Supplies will be delivered to the participating agency in accordance with required delivery/receipt dates as specifically stated in the purchase order and, in accordance with paragraphs S-8, S-9, and S-10 of the SUPPLEMENTAL CONTRACT TERMS AND CONDITIONS. The delivery location will be noted on the purchase order issued by the participating agency. 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.

Delivery locations will be to the Ohio Department of Mental Health and Addiction Services (ODMHS), Office of Support Services, 2150 West Broad Street, Columbus, Ohio 43223 and to a third party distributor's warehouse located at 4100 Quest Way, STE 114, Memphis, TN 38115. Orders placed by the Ohio Department of Health (ODH) are shipped to the third party distributor's warehouse.

Note: As of the issuance of this ITB, it is estimated that 5,000 - 10,000 doses will be shipped to the Memphis, TN location.

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 to arrive at an extended price 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.

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 three (3) 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: Ryan Beers.

OHIO LICENSE: All bidders must hold a current Ohio Wholesale Distributor of Dangerous Drug License since the products offered are dangerous (legend) drugs. Bidder shall include a copy of their current Ohio Wholesale Distributor of Dangerous Drug License as part of their bid response. If not provided as part of the bid response, the Bidder must provide proof within five (5) business days after request/notification by the Office of Procurement Services to do so. Failure to provide a copy of a current Ohio Wholesale Distributor of Dangerous Drug License will deem the bidder 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 seven (7) calendar 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.

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

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.

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.

SPECIFICATIONS

I. SCOPE AND CLASSIFICATION:

- A. Scope: The State of Ohio, Department of Administrative Services (DAS), Office of Procurement Services, on behalf of the Ohio Department of Health (ODH) and the Ohio Department of Mental Health and Addiction Services (ODMHS), is seeking bids for Influenza Vaccines, 2016-2017 year. The term of any contract issued pursuant to this ITB shall be approximately twelve (12) months from March 1, 2016 through February 28, 2017.
- B. Classification
1. Influenza Virus Vaccine, Inactivated, Trivalent, 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 2016-2017 year. This type is also known as TIV, IIV3, and cclIV3 (cell culture based IIV3).
 2. Influenza Virus Vaccine, Inactivated, Quadrivalent, 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 2016-2017 year. This type is also known as QIV and IIV4.
 3. Influenza Virus Vaccine Live Attenuated, Quadrivalent, 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 2016-2017 year. This type is also known as LAIV and LAIV4.

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
- E. Applicable sections(s) of the Drug Quality and Security Act
- F. Title II of the Drug Quality and Security Act of 2013, the Drug Supply Chain Security Act

SPECIFICATIONS (Cont'd.)

III. REQUIREMENTS

A. Products

1. Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials.
Reference # 210-80-1359V.
2. Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult No Preservative Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes (packaged in boxes of 10 Pre-Filled Syringes / box).
Reference # 210-80-1359S.
3. Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult No Preservative Formulation, IIV4, 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 2016-2017 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).
Reference # 210-80-1360S.
4. Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET), in Non-Returnable, 10-Dose, 5 ml Vials.
Reference # 210-80-1360V.
5. Influenza Virus Vaccine, Inactivated, Quadrivalent, Pediatric No Preservative Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET), in Single-Dose, 0.25 ml Pre-Filled Syringes (packaged in boxes of 10 Pre-Filled Syringes / box).
Reference # 210-80-1359.
6. Influenza Virus Vaccine, Live Attenuated, Quadrivalent, Intranasal Spray, LAIV4, 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 2016-2017 year, including Federal Excise Tax (FET), in Single-Use, 0.2 ml Sprays (packaged in boxes of 10 Single-Use Sprays / box).
Reference # 210-80-1361.

SPECIFICATIONS (Cont'd.)

7. Influenza Virus Vaccine, Inactivated, Trivalent, Adult High-Dose Preservative Free Formulation, IIV3, 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 2016-2017 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).
Reference # 210-80-1358S.
 8. Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult Intradermal Preservative Free Formulation, IIV4, 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 2016-2017 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.
Reference # 210-80-1357S.
 9. Influenza Virus Vaccine, Inactivated, Trivalent, Adult Formulation, Cell-Based ccIIV3, 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 2016-2017 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes, Luer Lock, (packaged in boxes of 10, or less, Pre-Filled Syringes / box). (Example: Novartis Flucelvax, or equivalent).
Reference # 210-80-1356S.
 10. Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult Preservative Free Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET), in Single-Dose, 0.5 ml Pre-Filled Syringes (packaged in boxes of 10 Pre-Filled Syringes / box).
Reference # 210-80-1361S.
- B. **Contract Usage:** The State may elect to participate in any Centers for Disease Control (CDC) contract that may be available to the State.
- C. **Compliance:** Manufacturing firms of the supplied items shall adhere to the most updated regulations under the Federal Food, Drug, and Cosmetic Act, as well as approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), Title II of the Drug Quality and Security Act, and applicable sections under Title 21 Code of Federal Regulations labeled 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.

SPECIFICATIONS (Cont'd.)

- 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.

- 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.

ITEM PRICE PAGES

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 (truncated) by the State, DAS Office of Procurement Services, and not used in the evaluation and any subsequent award. Bidder shall fill out columns C, D, H, and I. Failure to complete these sections may deem the bidder as not responsive. Federal Excise Tax (FET) shall be included in the per dose price in column I.

A	B	C	D	E	F	G	H	I
ITEM I.D. NO.		ITEM OFFERED	MANUFACTURER NAME AND PLANT LOCATION	UNIT SIZE	UNIT QTY.	EST. YEARLY REQ.	N.D.C. NUMBER	(Including FET) PRICE PER DOSE
REFERENCE NO.	ITEM REQUESTED							
29247 210-80-1359V	Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult Formulation, IIV4, licensed for administration to ages 6 months and over, to include the Antigens as formulated in accordance with the Centers or Disease Control and Prevention (CDC), prevention and control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP) for the 2016-2017 year, including Federal Excise Tax (FET).	Fluzone Quadrivalent Multi-dose Vial	Contractor: Henry Schein, Inc. Manufacturer: Sanofi Pasteur Plant Location: Swiftwater, PA	5 ml vial containing 10 total Doses. Each dose is .5 ml	Each Vial	* ** Unknown	Currently unknown will be added when manufacturer makes it available	\$ 15.40
29248 210-80-1359S	Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult No Preservative Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET).	Fluarix Quadrivalent	Contractor: H.D. Smith, LLC Manufacturer: GlaxoSmithKline Plant Location: Germany	Single Dose 0.5 ml	Fill-In: <u>10</u> Syr./Box	** (22,410 Doses)	58160-0905-52	\$ 16.484

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

** The combined total estimated usage quantity is 32,580 doses. Awarded contract prices may strongly affect the actual usage distribution among the line items.

ITEM PRICE PAGES (Cont'd.)

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 (truncated) by the State, DAS Office of Procurement Services, and not used in the evaluation and any subsequent award. Bidder shall fill out columns C, D, H, and I. Failure to complete these sections may deem the bidder as not responsive. Federal Excise Tax (FET) shall be included in the per dose price in column I.

A	B	C	D	E	F	G	H	I
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
29249 210-80-1360S	Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult No Preservative Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET).	Flucelvax Quadrivalent	Contractor: H.D. Smith, LLC Manufacturer: Seqirus Plant Location: Holly Springs, NC	Single Dose 0.5 ml	Fill-In: <u>10</u> Syr./ Box	* ** Unknown	Currently unknown will be added when manufacturer makes it available	\$ 15.285
29250 210-80-1360V	Influenza Virus Vaccine, Inactivated, Quadrivalent, Adult Formulation, IIV4, 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 2016-2017 year, including Federal Excise Tax (FET).	Fluzone Quadrivalent Multi-dose Vial	Contractor: Henry Schein, Inc. Manufacturer: Sanofi Pasteur Plant Location: Swiftwater, PA	5 ml vial containing 10 total Doses. Each dose is .5 ml	Each Vial	* ** Unknown	Currently unknown will be added when manufacturer makes it available	\$ 15.40

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

** The combined total estimated usage quantity is 32,580 doses. Awarded contract prices may strongly affect the actual usage distribution among the line items.

CONTRACTOR INDEX

CONTRACTOR AND TERMS:

CONTRACT NO: OT00908358-1

228305
H.D. Smith, LLC
960 Lively Blvd.
Wood Dale, IL 60191

TERMS: Net 30 Days

DELIVERY: Per ITB

Remit to address:
H.D. Smith, LLC
Dept 78709
Detroit, MI 48278-0709

CONTRACTOR'S CONTACT: Tim Navin

Telephone: (630) 616-0244
FAX: (630) 227-9220
E-mail: tim.navin@smpspecialty.com

Preferred method of receiving purchase orders is by email to tim.navin@smpspecialty.com .

NOTES:

Pre-book orders must be placed no later than April 30, 2016, for number of doses reserved.

CONTRACTOR AND TERMS:

CONTRACT NO: OT00908358-2

6512
Henry Schein, Inc.
135 Duryea Road E217
Melville, NY 11747

TERMS: Net 30 Days

DELIVERY: Per ITB

Purchase Order and Remit to address:
Henry Schein, Inc.
Box 382060
Pittsburg, PA 15250-8060

CONTRACTOR'S CONTACT: Annemarie Hoffmann

Telephone: (631) 390-8123
FAX: (866) 738-8999
E-mail: biddept@henryschein.com

Preferred method of receiving purchase orders is by email to biddept@henryschein.com Attn: Annemarie Hoffman.

NOTES:

Pre-book orders must be placed no later than March 31, 2016, for number of doses reserved.