



**RETURN BIDS TO:
RETOURNER LES SOUMISSIONS À:**

**Bid Receiving - PWGSC / Réception des
soumissions - TPSGC**
11 Laurier St. / 11, rue Laurier
Place du Portage , Phase III
Core 0B2 / Noyau 0B2
Gatineau, Québec K1A 0S5
Bid Fax: (819) 997-9776

**REQUEST FOR PROPOSAL
DEMANDE DE PROPOSITION**

**Proposal To: Public Works and Government
Services Canada**

We hereby offer to sell to Her Majesty the Queen in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods, services, and construction listed herein and on any attached sheets at the price(s) set out therefor.

**Proposition aux: Travaux Publics et Services
Gouvernementaux Canada**

Nous offrons par la présente de vendre à Sa Majesté la Reine du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens, services et construction énumérés ici sur toute feuille ci-annexée, au(x) prix indiqué(s).

Comments - Commentaires

Vendor/Firm Name and Address

**Raison sociale et adresse du
fournisseur/de l'entrepreneur**

Issuing Office - Bureau de distribution

Drugs, Vaccines and Biologics Division/Div.des produits
pharmaceutiques,biologiques et de vaccins
11 Laurier St. / 11, rue Laurier
6B3, Place du Portage III
Gatineau
Quebec
K1A 0S5

Title - Sujet Rotavirus	
Solicitation No. - N° de l'invitation E60PH-17ROTA/A	Date 2017-11-03
Client Reference No. - N° de référence du client E60PH-17ROTA	
GETS Reference No. - N° de référence de SEAG PW-\$\$PH-884-73685	
File No. - N° de dossier ph884.E60PH-17ROTA	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2017-11-22	Time Zone Fuseau horaire Eastern Standard Time EST
F.O.B. - F.A.B. Plant-Usine: <input type="checkbox"/> Destination: <input type="checkbox"/> Other-Autre: <input type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Joy(ph884), Sharon	Buyer Id - Id de l'acheteur ph884
Telephone No. - N° de téléphone (819) 420-2964 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction: See Herein	

Instructions: See Herein

Instructions: Voir aux présentes

Delivery Required - Livraison exigée	Delivery Offered - Livraison proposée
Vendor/Firm Name and Address Raison sociale et adresse du fournisseur/de l'entrepreneur	
Telephone No. - N° de téléphone Facsimile No. - N° de télécopieur	
Name and title of person authorized to sign on behalf of Vendor/Firm (type or print) Nom et titre de la personne autorisée à signer au nom du fournisseur/ de l'entrepreneur (taper ou écrire en caractères d'imprimerie)	
Signature	Date

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TITLE Rotavirus Vaccine

PART 1 - GENERAL INFORMATION

1.1 Security Requirement

There is no security requirement associated with this bid solicitation.

1.2 Requirement

The requirement is detailed under Article 6.2 of the resulting contract clauses.

1.3 Debriefings

Bidders may request a debriefing on the results of the bid solicitation. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be provided in writing, by telephone or in person.

1.4 Trade Agreements

The requirement is subject to the provisions of the Canadian Free Trade Agreement (CFTA).

PART 2 - BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

- (a) All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the Standard Acquisition Clauses and Conditions Manual (<http://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.
- (b) Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.
- (c) The 2003 (2017-04-27) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.
- (d) Subsection 5.4 of 2003, Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: 60 days
Insert: 180 days

2.2 Submission of Bids

Bids must be submitted only to PWGSC Bid Receiving Unit by the date, time and place indicated on page 1 of the bid solicitation.

2.3 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than five (5) calendar days before the bid closing date. Enquiries received after that time may not be answered.

Bidders should reference as accurately as possible the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated, and the enquiry can be answered to all Bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

2.4 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in the province of Ontario.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

PART 3 - BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

(a) Canada requests that bidders provide their bid in separately bound sections as follows:

- (i) Section I: Technical Bid (1 hard copy)
- (ii) Section II: Financial Bid (1 hard copy)
- (iii) Section III: Certifications (1 hard copy)

Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.

(b) Canada requests that Bidders follow the format instructions described below in the preparation of their bid:

- (i) use 8.5 x 11 inch (216 mm x 279 mm) paper;
- (ii) use a numbering system that corresponds to the bid solicitation.

(c) In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary steps to incorporate environmental considerations into the procurement process Policy on Green Procurement (<http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html>). To assist Canada in reaching its objectives, Bidders should:

- (i) use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and containing minimum 30% recycled content; and

- (ii) use an environmentally-preferable format including black and white printing instead of colour printing, printing double sided/duplex, using staples or clips instead of cerlox, duotangs or binders.

3.2 Section I: Technical Bid

- (a) In their technical bid, Bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.
- (b) For each vaccine proposed, the Bidder must provide:
 - (i) Drug Identification Number (DIN); or
 - (ii) Evidence that the Bidder has submitted a duly completed New Drug Submission to Health Canada, Biologics and Genetic Therapies Directorate (BGTD), no later than the closing date of this RFP and that BGTD has accepted the submission for review. A copy of the application and proof of acceptance of the submission for review by BGTD must be included.
- (c) **Bid Submission Form:** Bidders are requested to include the Bid Submission Form – Form 1 with their bids. It provides a common form in which bidders can provide information required for evaluation and contract award, such as a contact name and the Bidder's Procurement Business Number, etc. Using the form to provide this information is not mandatory, but it is recommended. If Canada determines that the information required by the Bid Submission Form is incomplete or requires correction, Canada will provide the Bidder with an opportunity to do so.

3.3 Section II: Financial Bid

- (a) Bidders must submit their financial bid in accordance with the Basis of Payment.
- (b) The quantities provided in Basis of Payment and the delivery schedules are only an approximation of requirements given in good faith. The quantities specified are subject to change prior to Contract award. Each Identified Users reserves the right to alter quantities or to withdraw from participation for any given item up until Contract award. A quantity change, which represents a significant change in the Requirement for an item, may result in a decision to re-tender that item.

3.3.1 SACC Manual Clauses

- (a) C3011T (2013-11-06) - Exchange Rate Fluctuation
- (b) A9033T (2012-07-16) - Financial Capability

3.4 Section III: Certifications

Bidders must submit the certifications and additional information required under Part 5.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

4.1 Evaluation Procedures

- (a) Bids will be assessed in accordance with the entire requirement of the bid solicitation including the technical and financial evaluation criteria.

- (b) An evaluation team composed of representatives of Canada will evaluate the bids.

4.1.1 Technical Evaluation - Mandatory Technical Criteria

A bid must comply with the requirements of the bid solicitation and meet all mandatory technical evaluation criteria to be declared responsive.

4.1.2 Financial Evaluation

Canada will calculate an evaluated price for each item listed in Annex B based on its total price over both the firm and option years. For evaluation purposes only, an administrative cost of \$12.00 per dose will be added to the unit price. The evaluated price for each item will be calculated as follows:

[Year 1 total number of infants x number of doses per infant x (Year 1 unit price + \$12.00)] +
[Year 2 total number of infants x number of doses per infant x (Year 2 unit price + \$12.00)] +
[Year 3 total number of infants x number of doses per infant x (Year 3 unit price + \$12.00)]

4.2 Basis of Selection

- (a) A bid must comply with the requirements of the bid solicitation and meet all mandatory evaluation criteria to be declared responsive.
- (b) For each item in Annex B, the responsive bid with the lowest evaluated price will be recommended for award of a contract.
- (c) If there are two or more bids with identical lowest evaluated prices, the names of all Bidders with identical lowest bid prices will be placed in a hat and the winner will be the first name drawn from it. All Bidders with the lowest bid price will be invited to witness the event.

PART 5 – CERTIFICATIONS AND ADDITIONAL INFORMATION

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the bidder's certification. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

5.1 Certifications Required with the Bid

Bidders must submit the following duly completed certifications as part of their bid.

5.1.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, if applicable, the declaration form available on the Forms for the Integrity Regime website (<http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html>) to be given further consideration in the procurement process.

5.2 Certifications Precedent to Contract Award and Additional Information

The certifications and additional information listed below should be submitted with the bid, but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame provided will render the bid non-responsive.

5.2.1 Integrity Provisions – Required Documentation

In accordance with the section titled Information to be provided when bidding, contracting or entering into a real procurement agreement of the Ineligibility and Suspension Policy (<http://www.tpsgc-pwgsc.gc.ca/ci-if/politiquepolicy-eng.html>), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

5.2.2 Federal Contractors Program for Employment Equity - Bid Certification

- (a) By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "FCP Limited Eligibility to Bid" list available at the bottom of the page of the Employment and Social Development Canada (ESDC) - Labour's website (<https://www.canada.ca/en/employment-social-development/programs/employmentequity/federal-contractorprogram.html#>)
- (b) Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the "FCP Limited Eligibility to Bid" list at the time of contract award.
- (c) Canada will also have the right to terminate the Contract for default if a Contractor, or any member of the Contractor if the Contractor is a Joint Venture, appears on the "FCP Limited Eligibility to Bid" (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/list/inelig.shtml) list during the period of the Contract.
- (d) The Bidder must provide the Contracting Authority with a completed annex titled Federal Contractors Program for Employment Equity - Certification, before contract award. If the Bidder is a Joint Venture, the Bidder must provide the Contracting Authority with a completed annex Federal Contractors Program for Employment Equity - Certification, for each member of the Joint Venture.

PART 6 - RESULTING CONTRACT CLAUSES

6.1 Security Requirement

There is no security requirement applicable to this Contract.

6.2 Requirement

The Contractor must provide the items detailed under the Requirement at Annex A to Identified Users as listed in Annex C.

6.3 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in Standard Acquisition Clauses and Conditions Manual(<http://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.

6.3.1 General Conditions

2010A (2016-04-04) General Conditions - Goods - Medium Complexity, apply to and form part of the Contract.

6.3.2 Warranty - Amendment to General Conditions 2010A

Section 09, paragraph 1, of General Conditions 2010A, which forms part of the Contract will not apply to Work with a specified expiry date. The following paragraph replaces section 9, paragraph 1, General Conditions 2010A for Work with a specified expiry date:

- (a) Despite inspection and acceptance of the Work by or on behalf of Canada and without restricting any other provision of the Contract or any condition, warranty or provision implied or imposed by law, the Contractor warrants that the Work conforms to the specifications until the expiration date required by the Requirement. The Contractor must, upon the request of Canada, replace at its own expense including costs of returns and delivery of replacement Work as soon as possible any supplies that fail to conform or that deteriorates prior to the expiration date required by the Requirement.
- (b) If full replacement is not available in a timeframe acceptable to Canada, then Canada may, in addition to and without prejudice to any other remedy available, choose from one of the following options for the quantity and Contract value of the Work affected:
 - (i) Full and immediate reimbursement;
 - (ii) Equivalent full credit against future purchases under the Contract; or
 - (ii) Partial replacement and partial reimbursement or partial credit.

6.4 Term of Contract

6.4.1 Period of Contract

The period of the Contract is from April 1, 2018 to March 31, 2019, inclusive.

6.4.2 Option to Extend the Contract

- (a) The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to two additional one (1) year period under the same conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable provisions as set out in the Basis of Payment.
- (b) Canada may exercise this option at any time by sending a written notice to the Contractor at least 90 calendar days before the expiry date of the Contract. The option may only be exercised by the Contracting Authority, and will be evidenced for administrative purposes only, through a contract amendment.

6.4.3 Option to Add Identified User

Subject to the mutual agreement of the Contractor and Canada, additional Identified Users may be added to the Contract at a price not to exceed the Contract price and subject to the same conditions.

6.5 Authorities

6.5.1 Contracting Authority

- (a) The Contracting Authority for this Contract is:

Sharon Joy
Supply Specialist
Public Works and Government Services Canada
Drugs, Vaccines & Biologics
Place du Portage, Phase III, 6B3
11 Laurier Street
Gatineau, QC K1A 0S5

Telephone: (819) 420-2964
Facsimile: (819) 956-7340
Email address: sharon.joy@pwgsc-tpsgc.gc.ca

- (b) The Contracting Authority is responsible for the management of the Contract and the Contracting Authority must authorize any changes to the Contract in writing. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

6.5.2 Identified Users

- (a) The list of Identified Users is provided in Annex C.
- (b) The Identified Users are the representatives of the department, agency, province or territory for whom the Work is being carried out under the Contract. The Identified Users have no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

6.5.3 Canada and Public Works and Government Services as Agent

- (a) The Contractor acknowledges that Canada is acting as an agent for Identified Users. Canada will only be funding and paying for Orders placed on behalf of a Federal Government Department or Agency.
- (b) Orders placed by or on behalf of a non-Federal Government Department or Agency Identified User under the Contract are the responsibility of the Identified User for whom or by whom the Order is placed. To the extent that the Contract involves orders placed by Canada on behalf of a non-Federal Government Department or Agency Identified User, Canada is acting as an agent for the Identified User only and the Identified User is solely liable and responsible for funding and payment of those orders.
- (c) The Contractor acknowledges and agrees that, unless otherwise specified, Canada is not liable under the Contract to the extent that it involves Orders placed on or on behalf of a non-Federal Government Department or Agency Identified User, and the Contractor agrees that it must not make any claim or take any proceeding against Canada for any loss, damages, or non-payment in any way related to or arising out of such Orders.

6.5.4 Contractor Representative

NOTE TO BIDDER: Please include the requested information on "FORM 1 - BID SUBMISSION".

(a) General enquiries:

Name: _____
Telephone No.: _____
Facsimile No.: _____
E-mail address: _____

(b) Delivery follow-up:

Name: _____
Telephone No.: _____
Facsimile No.: _____
E-mail address: _____

6.6 Ordering

6.6.1 Order against Contract

- (a) The Work to be performed under the Contract will be on an "as and when requested basis" using an Order against Contract ("Order").
- (b) **Process for Issuing an Order:** If a requirement is identified, an Order will be prepared by the Identified User and sent to the Contractor by letter, by e-mail, or by telephone, or any other means agreed to by the parties and evidenced in writing.
- (c) **Contents of an Order:** The Order must contain the following information, if applicable:
- (i) An order number;
 - (ii) price, quantity and description of goods being ordered;
 - (iii) delivery location;
 - (iv) invoicing address; and
 - (v) any other constraints that might affect the work.
- (d) **Delivery:** Unless otherwise indicated in the Order, delivery must be made within seven (7) calendar days from receipt of an Order.
- (e) **Charges for Work under a Order:** The Contractor must not charge the Identified User anything more than the price set out in the Order unless the Identified User has issued an Order amendment authorizing the increased expenditure. The Identified User will not pay the Contractor for any design changes, modifications or interpretations of the Work unless they have been approved, in writing, by the Contracting Authority before being incorporated into the Work.
- (f) **Consolidation of Orders for Administrative Purposes:** The Contract may be amended from time to time to reflect all Orders issued to date, to document the Work performed under those Orders for administrative purposes.

6.6.2 Minimum Work Guarantee - All the Work

- (a) In this clause,

"Maximum Contract Value" means the amount specified in the "Limitation of Expenditure" clause set out in the Contract; and

"Minimum Contract Value" means \$ (to be inserted at contract award).

- (b) Canada's obligation under the Contract is to request Work in the amount of the Minimum Contract Value or, at Canada's option, to pay the Contractor at the end of the Contract in accordance with paragraph (c). In consideration of such obligation, the Contractor agrees to stand in readiness throughout the Contract period to perform the Work described in the Contract. Canada's maximum liability for work performed under the Contract must not exceed the Maximum Contract Value, unless an increase is authorized in writing by the Contracting Authority.
- (c) In the event that Canada does not request Work in the amount of the Minimum Contract Value during the period of the Contract, Canada must pay the Contractor the difference between the Minimum Contract Value and the total cost of the Work requested.
- (d) Canada will have no obligation to the Contractor under this clause if Canada terminates the Contract in whole or in part for default.

6.6.3 Point of Manufacturing and Shipping

NOTE TO BIDDER: Please include the requested information on "FORM 1 - BID SUBMISSION".

Contractor's Point of Manufacturing is located at: _____

Contractor's Shipping Facilities are located at: _____

6.6.4. Packaging

Packaging for the Work must clearly indicate on packing slips and on the outside of outer packages and cartons, as applicable, the following:

- (a) On each package and carton:
 - (i) Contractor's Name;
 - (ii) Manufacturer's Brand Name;
- (b) On each package, carton, vial, ampoule, bottle, and pre-filled syringe (if applicable) the following:
 - (i) Drug Identification Number (DIN) and NATO Stock Number (NSN) (if applicable);
 - (ii) Global Trade Identification Number (GTIN) (if applicable);
 - (iii) Lot Number; and
 - (iv) Expiry Date.
- (c) Identify the carton(s) which contain the packing slip. If the Contractor will use the GTIN, then Bar codes on shipping package (i.e., shrink wrapped product), secondary and primary package, including variable data, must comply with GS1 standards and the Canadian Automated Identification of Vaccine Products process (if applicable);
- (d) The Contractor must identify partly packed carton(s) and box(es).
- (e) Packaging is to be in accordance with good commercial standards to ensure safe arrival at destination. In addition to the Contract Requirement, the Contractor must ensure that all goods

are properly labeled and packaged in compliance with the Biologics and Genetic Therapies Directorate (BGTD) Regulations.

- (f) Over the period of the Contract, the Contractor may offer other packaging options consistent with emerging technology. Canada retains the right to refuse such offerings.

6.6.5 Shipping Instructions

- (a) Goods must be consigned to the destinations specified in the Order and delivered DDP Delivered Duty Paid (Identified User), Incoterms 2000 for shipments from a commercial contractor.
- (b) All Orders by following Identified Users must be delivered by air transport, unless the contracting Authority or the following Identified Users has specifically requested, and has agreed in writing, to have a delivery made by ground transport:
- (i) Newfoundland and Labrador;
 - (ii) Nunavut;
 - (iii) Yukon Territories; and
 - (iv) Northwest Territories.

6.6.6 Maintenance of the Cold Chain During Transportation and the Use of Cold Chain Monitors.

- (a) The Contractor must maintain the vaccine:
- (i) at or between 2 to 8 degrees Celsius, or
 - (ii) as stated on the product label, or
 - (iii) in accordance with temperature conditions supported by stability data
- throughout transport from the Contractor to the Identified User ("Transport Conditions"). The Contractor must provide evidence to that effect from the data analysis of the temperature monitoring device or carrier logs, as applicable.
- (b) The Contractor must use a continuous electronic monitoring device and a receiving notice specifying acceptance criteria must be included in the shipment. At the request of a Identified User, a color cold chain chemical indicator (heat and freeze) may be used.
- (c) In the case of the use of a continuous electronic temperature-monitoring device, the Identified User will accept the Work on a conditional basis until a Certificate of Conformity is received. The Contractor must provide a Certificate of Conformity to the Identified User within three (3) business days of the Contractor's receipt of the monitoring device or the device's data in the case of an electronic information transfer. Unless the monitoring device is disposable, the Identified User will return all electronic monitoring devices to the Contractor within 24 hours of receiving the Work.
- (d) A written "Certificate of Conformity" confirms that:
- (i) the required Transport Conditions were maintained during transport;
 - (ii) the integrity and quality of the vaccine has not been affected by temperature excursions during transport, and
 - (iii) the expiry date of the Work as indicated on the vaccine packaging has not been impacted by temperature excursions during transport.
- (e) The Contractor must maintain a record of the shipment and transport data when using an electronic monitoring device for the purpose of addressing any future enquiries from the Identified User. The Contractor must keep these records, as a minimum, until 12 months after the expiry

date of the Work, as indicated on the vaccine packaging label or 12 months following the end of the period of the Contract, whichever is the later.

- (f) Failure of the Contractor to provide a Certificate of Conformity within this timeframe will entitle the Identified User to return the product to the Contractor for full replacement at no additional cost to the Identified User.
- (g) Acceptance by an Identified User of a shipment not meeting the Transport Conditions is not a waiver of Transport Conditions for future shipments experiencing similar Transport Conditions either by the Identified User in question or by other Identified Users.
- (h) During the evaluation of the Transport Conditions by the Contractor, the Identified User will ensure that the Work is maintained according to the storage recommendations stated in the product monograph.

6.6.7 Dangerous Goods/Hazardous Products

- (a) The Contractor must ensure proper labeling and packaging in the supply and shipping of dangerous goods/hazardous products to the Identified User.
- (b) The Contractor will be held liable for any damages caused by improper packaging, labeling or carriage of dangerous goods/hazardous products.
- (c) The Contractor must clearly mark all merchandise labels with the percentage of volume that is a hazardous item. Failure to do so will result in the Contractor being held responsible for damages caused in the movement of goods/products by government vehicles or government personnel.
- (d) The Contractor must adhere to all applicable laws regarding dangerous goods/hazardous products.

6.7 Payment

6.7.1 Basis of Payment - Firm Unit Price(s) or Firm Lot Price

In consideration of the Contractor satisfactorily completing all of the obligations under the Contract, the Contractor will be paid a firm unit price as specified in Annex B.

6.7.2 Limitation of Expenditure - Cumulative Total of all Orders

- (a) Canada's total liability to the Contractor under the Contract for all Orders, inclusive of any revisions, must not exceed the sum of \$ (*to be inserted at contract award*). Customs duties are included and Applicable Taxes are extra.
- (b) No increase in the total liability of Canada will be authorized or paid to the Contractor unless an increase has been approved, in writing, by the Contracting Authority.

6.7.3 SACC Manual Clauses

- (a) C6000C (2017-08-17), Limitation of Price
- (b) H1001C (2008-05-12), Multiple Payments

6.8 Invoicing Instructions

-
- (a) The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.
- (b) The original and one copy of all invoices are to be forwarded to each Identified User for certification and payment at the Invoicing address specified at Annex C.

6.9 Product Recall or Withdrawal

- (a) In the event of a recall or a withdrawal of Work, the Contractor must notify the Contracting Authority and all Identified Users who have been delivered the recalled or withdrawn Work and must collect and destroy the delivered, recalled, or withdrawn Work at their own cost.
- (b) The Contractor must, upon the request of Canada or an Identified User, replace as soon as possible any recalled or withdrawn Work at their own cost.
- (c) If full replacement is not available in a timeframe acceptable to Canada or an Identified User, then Canada or the Identified User may, in addition to and without prejudice to any other remedy available, choose from one of the following options for the quantity and Contract value of the Work affected:
- (i) Full and immediate reimbursement;
 - (ii) Equivalent full credit against future purchases under the Contract; or
 - (iii) Partial replacement and partial immediate reimbursement or partial credit under the Contract.

6.10 Product Dating

All Work supplied must have a shelf life of no less than 12 months remaining on the date of delivery, unless prior authorization is obtained from the Contracting Authority / Identified User (as Applicable). Failure to obtain authorization may result in the return of the shipment, at the Contractor's cost.

6.11 Returns

In addition to and without prejudice to any other remedy available, for work:

- (a) Damaged during shipment from Contractor, the Contractor must provide full credit or replacement or refund for all returned Work where Contractor was contacted within 5 days of delivery to and acceptance by the Identified User. Damaged Work will be returned FCA Free Carrier (Identified user) Incoterms 2000 to the address specified below. The Contractor is responsible for shipping costs.
- (b) That has expired which had a shelf life of less than 12 months upon delivery to and acceptance by the Identified User, the Contractor must provide full credit or replacement or refund for all expired, unopened Work returned with the original packing slip within one (1) year after expiry date. Returns are to be shipped FCA Free Carrier (Identified User) Incoterms 2000 to the address indicated below. The Contractor is responsible for shipping costs.
- (c) That had a minimum shelf life of 12 months upon delivery to and acceptance by the Identified User, up to five percent (5%) of the of quantity purchased under the Contract may be returned to the Contractor for full credit in the amount of the invoiced price. Returns must be expired, unopened Work and returned with the original packing slip within one (1) year after expiry to be shipped DDP Delivery Duty Paid (to the address indicated below) Incoterms 2000 by the Identified User. The Identified User is responsible for shipping costs.

(d) Contractor's Returns Facilities:

NOTE TO BIDDER: Please include the requested information on "FORM 1 - BID SUBMISSION".

Address:
Contact Name:
Telephone:
Facsimile:
Email:

6.12 Notice of Anticipated Shortage

- (a) The Contractor must notify the Contracting Authority when it becomes aware of a potential problem, delay, or event that may lead to a shortage of any of the quantities listed in Annex B. Such notice must include a description of the nature of the problem or delay or event, the anticipated impact on the requirements of the Contract, the steps being taken by the Contractor to rectify the situation or to minimize the impact on this Contract, and the expected date by which the shortage will be fully corrected.
- (b) For the purpose of this clause "shortage" is defined as the inability to meet an Order in full or the failure to maintain the minimum stockpile

6.13 Inability to Supply

- (a) In the event that the Contractor is unable to supply the Work in accordance with the terms and conditions of the Contract, whether as the result of vaccine discontinuation or for any other reason, the Contractor will provide a substitute product acceptable to the Identified User at a price no greater than firm unit price specified in Annex B.
- (b) Should the Identified User be required to purchase the Work from an alternate source at a higher price, the Contractor must reimburse the Identified User for the difference between the price paid to the alternate source and the firm unit price specified in Annex B.
- (c) Should the Identified User be required to purchase the Work from an alternate source, Canada reserves the right to adjust the final total estimated quantity in the Contract.

6.14 Stockpile

- (a) At all time during the period of the Contract, the Contractor must maintain a minimum stockpile of 20% finished stock (stored in Canada and released by BGTD) for each item included in the Work. It is the Contractor's sole responsibility to rotate the stockpile as necessary to ensure that a minimum of twelve (12) month shelf-life is maintained. The stockpile is subject to inspection by Canada at anytime during the period of the Contract.
- (b) Ninety (90) days prior to the end of the contract period, if an option to extend the period of the contract has not been exercised, the Contractor will be permitted to draw down against the full amount of the stockpile.
- (c) Throughout the period of the Contract, the Contractor must provide a monthly report summarizing the status and maintenance of the stockpile. As a minimum, the report will include: the amount of doses contained in stockpile and the shelf life of the stockpile. The monthly report must be submitted in an electronic format to the Contract Authority by the first Monday of every month.

6.15 Reporting

6.15.1 Periodic Usage Reports:

The Contractor must provide a monthly report for each item. The monthly report must be submitted in an electronic format to the Contracting Authority by the first Monday of the every month. The monthly report must summarize the following:

- (a) Orders by Identified Users on a month by month basis;
- (b) Percentage of commitment fulfilled by each Identified User;
- (c) Status of Working Inventory including number of doses of the Work currently on hand, date of availability of next Health Canada released lot, number of doses (or duration of expected supply) of next Health Canada released lot; and
- (d) Status and maintenance of the Stockpile. At a minimum, the amount of doses contained in the Stockpile and the shelf life of the Stockpile must be provided.

6.15.2 Adverse Event Following Immunization (AEFI) Reporting Requirement

The Contractor must comply with all Identified Users' AEFI reporting requirements.

6.16 Certifications

6.16.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

6.16.2 Federal Contractors Program for Employment Equity - Default by the Contractor

The Contractor understands and agrees that, when an Agreement to Implement Employment Equity (AIEE) exists between the Contractor and Employment and Social Development Canada (ESDC) - Labour, the AIEE must remain valid during the entire period of the Contract. If the AIEE becomes invalid, the name of the Contractor will be added to the "FCP Limited Eligibility to Bid" list. The imposition of such a sanction by ESDC will constitute the Contractor in default as per the terms of the Contract.

6.17 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in the province of Ontario.

6.18 Priority of Documents

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

- (a) the Articles of Agreement;
- (b) the general conditions 2010A (2016-04-04) Goods (Medium Complexity);

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- (c) Annex A: Requirement;
- (d) Annex B: Basis of Payment;
- (e) Annex C: Identified Users and Delivery Points;
- (f) the Contractor's bid dated _____

6.19 Insurance

SACC Manual Clause G1005C (2016-01-28), Insurance – No Specific Requirement

ANNEX A - REQUIREMENT

1. Scope

The Contractor must supply rotavirus vaccine, duly authorized for sale in Canada.

2. Quantity

See Annex B - Basis of Payment

3. Vaccine Format (s)

Format(s): packs of 10 x1 single dose oral solution

4. Trace back Through Automated Identification of Vaccines

- (a) The Contractor must meet the current packaging requirements as described in the Contract. In addition, the Contractor must be prepared to implement automated identification of the Work supplied under this Contract in accordance with the recommendations and implementation schedule of the Canadian Automated Identification of Vaccine Product advisory committee. This obligation is also subject to any other requirements that may be specified by the Biologics and Genetic Therapies Directorate. If the Contractor is currently using automated identification of vaccine products or implements it during the life of the Contract, then the Contractor must provide details to the Identified Users on the contents of this system (e.g., what information is included in the bar code.) prior to delivery or implementation.
- (b) In the event that the Contractor plans to introduce a new Automated Identification of Vaccine Product system, the Contractor must first ensure that the Identified Users are advised and have implemented the appropriate technology to properly use the new Automated Identification of Vaccine Product system.

5. Timely Lot Release, Contractor's Responsibility

The Contractor must submit all vaccine lots to BGTD so as to ensure that the release of lots by the BGTD will occur early enough to allow the Contractor to meet the delivery requirements of the Contract.

6. Vaccine Identification Database System

- (a) The Contractor must provide the following information within 10 business days of a lot release by Biologics and Genetic Therapies Directorate of the Public Health Agency of Canada for the purpose of updating the Vaccine Identification Database System:
 - (i) GTIN (if applicable);
 - (ii) DIN;
 - (iii) Product
 - (iv) Lot Number; and
 - (v) Expiry date.
- (b) Data may be sent in either word or excel format to AIVP-IAVP@phac-aspc.gc.ca.

7. Provision of Educational Materials - Upon request

In support of all Work supplied under the contract, and in accordance with industry practice, the Contractor must provide bilingual (English and French) educational materials intended for use by public health practitioners if requested in Order.

7.1 Types and Content of Educational Material

(a) Educational materials to be provided by Contractor may include, but are not limited to:

- (i) provider instruction pamphlets;
- (ii) brochures;
- (iii) posters;
- (iv) product monographs (standard and large print); and
- (v) dosage cards.

Educational material is of particular importance if a vaccine is new to a Identified User; is targeted for specific populations (as opposed to use in the general population); or otherwise differs in use, administration, or format from the traditional multi-dose vial TIV currently used by the Identified Users.

(b) Educational materials must, as a minimum:

- (i) Include information relevant to the efficacy and onset of immunization coverage; the benefits of vaccination versus not being immunized; any potential adverse reactions and how to manage them; any potential interactions with other pharmaceutical products; guidelines for storage and use of the vaccine; the stability of product including continued stability if subject to temperature fluctuations (outside of recommended storage conditions); and the inter-changeability of the product with similar products.
- (ii) Contain or reference available scientific data related to efficacy, effectiveness, immunogenicity and safety in the anticipated target population including sub-segments (e.g. by age and medical conditions); and
- (iii) Provide instructions on mixing and re-constitution (if necessary) and on use and administration (including best practices, recommended syringe size and needle gauge / length for different populations, if any, instructions for ensuring all doses can be routinely withdrawn from a multi-dose vial, etc.).

7.2 Timing of Availability of Educational Materials

Educational materials should be provided in advance of shipments of the Work and in a timely manner so as to allow for advance preparation of recommendations, guidelines and surveillance programs. At the latest, educational materials must be provided with the deliveries and then on an on-going basis thereafter, highlighting any information that has changed.

ANNEX B - BASIS OF PAYMENT**1. Pricing Information**

All prices are firm unit prices, in Canadian dollars, transportation charges included, custom duties are included; and where applicable, zero rated for Goods and Services Tax (GST) or Harmonized Sales Tax (HST). Provincial sales taxes are not applicable. Each firm unit price is applicable for all destinations in Canada.

Item 001: Rotavirus Vaccine – Firm Year April 1, 2018 to March 31, 2019

Trade name: _____

Drug Identification Number (DIN): _____

Format(s): _____

Firm Year	Firm quantity	Quantity as doses	Firm Unit price (DDP Identified User)
2018-2019	Require sufficient quantity based on product monograph to immunize cohorts of 344,290 infants	infants x ____doses/infant = _____ Total doses	\$_____/dose

Item 002: Rotavirus Vaccine – Option Year 1 April 1, 2019 to March 31, 2020

Option Year 1 Year	Option quantity	Estimated Quantity as doses	Firm Unit price (DDP Identified User)
2019-2020	Require sufficient quantity based on product monograph to immunize cohorts of 345,373 infants	infants x ____doses/infant = _____ Total doses	\$_____/dose

Item 003: Rotavirus Vaccine – Option Year 2 April 1, 2020 to March 31, 2021

Option Year 2	Option quantity	Estimated Quantity as doses	Firm Unit price (DDP Identified User)
2020-2021	Require sufficient quantity based on product monograph to immunize cohorts of 346,469 infants	infants x ____doses/infant = _____ Total doses	\$_____/dose

2. Delivery Schedule:

- (a) The table below represents Canada's maximum estimated requirement*.
- (b) The actual monthly quantities requested on Identified Users' Orders may not conform to the estimated amounts.
- (c) In each year of the Contract, the Contractor is guaranteed to receive Orders totalling a minimum of 75% of the total annual maximum quantity. The total annual maximum quantity is 120% of quantities listed below.
- (d) If additional Identified Users are added to the Contract, their quantities will be in addition to the minimum and maximum quantities described above.

****Monthly Delivery schedule to be provided at contract award – below is the overall numbers by jurisdiction.***

FPT	Total Estimated # infants Firm Year 2018-19
AB	46,800
BC	43,200
MB	14,700
NB	8,000
NL	5,000
NT	350
NU	940
ON	135,000
PE	1,400
QC	75,000
SK	13,500
YK	400
Total	344,290

FPT	Total Estimated # infants Option Yr 1 2019-20
AB	47,736
BC	43,200
MB	14,847
NB	8,000
NL	5,000
NT	350
NU	940
ON	135,000
PE	1,400
QC	75,000
SK	13,500
YK	400
Total	345,373

FPT	Total Estimated # infants Option Yr 1 2019-20
AB	48,684
BC	43,200
MB	14,995
NB	8,000
NL	5,000
NT	350
NU	940
ON	135,000
PE	1,400
QC	75,000
SK	13,500
YK	400
Total	346,469

ANNEX C – IDENTIFIED USERS AND DELIVERY POINTS

Alberta	Alberta Health and Wellness Provincial Vaccine Depot 7802 - 101 Street Fort Saskatchewan, Alberta T8L 2P3 Att: Elaina / Marilyn / Stephanie 780 992 6980	Alberta Health and Wellness Surveillance & Assessment Branch Health System Accountability and Performance Division 23 rd Floor, ATB North Tower 10025 Jasper Avenue Edmonton, AB T5J 1S6 Attn: Julia Freda
British Columbia	Pharmacy Services British Columbia Centre for Disease Control 655 West 12th Avenue Suite 1100 Vancouver, BC V5Z 4R4 Att: Jim Sinclair, 604-707-2585	Pharmacy Services British Columbia Centre for Disease Control 655 West 12th Avenue Suite 1100 Vancouver, BC V5Z 4R4 Jim.Sinclair@bccdc.ca
Quebec	Logistics Support Unit Inc. (LSU) 1375 chemin Newton Boucherville, Québec J4B 5H2 A/S Vincent Lefebvre, Numéro de téléphone : 450 552-8083 x 1001	SigmaSanté 2953 rue Bélanger, bureau 202 Montréal, Québec H1Y 3G4 A/S Madame Stéphanie Plante, Numéro de téléphone : 514 376- 5600 x 227
Manitoba	Manitoba Health C/O MDA Unit#7-1715 St. James Street Receiving Door #24 Winnipeg, MB, R3H 1H3 Attn.: Robert Nicholls Phone: (204) 948-1327 or (204) 791-1084	Public Health Division, Manitoba Health Communicable Disease Control Branch 4060 – 300 Carlton Street Winnipeg, MB R3B 3M9 Attn: Inga Hossack
New Brunswick	NB Dept. of Health c/o Serum Depot Saint John Regional Hospital 400 University Avenue, Level Zero Saint John, NB, E2L 4L2 Att: Sally Kingston or Staci Leblanc 506-648-6474	SNB AP – c/o Dept. of Health PO Box 6000, SA – Pat Guest Fredericton, NB, E3B 5H1 1-888-487-5050 Email: invoices@snb.ca
Newfoundland/Labrador	Dept. of Health & Community Services Vaccine Program Miller Centre, 100 Forest Road	Dept. Of Health & Comm. Services Prov. Medical Officer of Health Dept. of Finance Corporate Financial Services

	St. John's, NL A1A 1E5 Att: Neil Butland, 709-729-3430	657 Topsail Road St. John's, NL A1E 2E3
Northwest Territories - Stanton Territorial Hospital	Stanton Territorial Hospital 550 Byrne Road Yellowknife, NT, X1A 2N1 Att: Kelly Irwin, 867-669-4118	Stanton Territorial Hospital 550 Byrne Road Yellowknife, NT, X1A 2N1 Attn: Finance
Northwest Territories - Inuvik Regional Hospital	Inuvik Regional Hospital Bag Service No. 2 Inuvik, NT, X0E 0T0 Att: Mark Bleakney, 867-777-8028	Inuvik Regional Hospital Beaufort Delta Health & Social Services Authority Bag Service No. 2 Inuvik, NT, X0E 0T0 Att: Wanda Storr, 867-777-8157
Northwest Territories - Yellowknife Public Health Unit	Yellowknife Public Health Unit 4702 Franklin Avenue Yellowknife, NT, X1A 2N5 Attn: Alanna Sorenson or Mary Lou Murphy 867-920-6212	Yellowknife Public Health Unit 4702 Franklin Avenue PO Box 608 Yellowknife, NT, X1A 2N5 Attn: Mary Lou Murphy 867-920-6212 Mary_Lou_Murphy@gov.nt.ca
Nunavut - Baffin Region	Qikiqtani General Hospital Pharmacy P.O. Box 1000, Stn. 1026 Iqaluit, NU, X0A 0H0 Att: Mike Gauvin, 867-975-8600 ext.: 2306	Qikiqtani General Hospital Pharmacy P.O. Box 1000, Stn. 1026 Iqaluit, NU, X0A 0H0 Att: Mike Gauvin, 867-975-8600 ext.: 2306
Nunavut - Kitikmeot Region	Kitikmeot Regional Hospital P.O. Box 53 13B Omingmak Street Cambridge Bay, NU X0B 0C0 Attn: Pharmacy, 867-983-4526	Qikiqtani General Hospital Pharmacy P.O. Box 1000, Stn. 1026 Iqaluit, NU, X0A 0H0 Att: Mike Gauvin, 867-975-8600 ext.: 2306
Nunavut - Kivalliq Region	Kivalliq Regional Health Centre 1-61 Tupirvik Street Rankin Inlet, NU, X0C 0G0 Attn: Amanda Arsenault, Pharmacy, 867-645-8334	Qikiqtani General Hospital Pharmacy P.O. Box 1000, Stn. 1026 Iqaluit, NU, X0A 0H0 Att: Mike Gauvin, 867-975-8600 ext.: 2306
Ontario	Ontario Ministry of Health and Long-Term Care OGPMSS Supply Chain and Facilities Branch 99 Adesso Drive Concord, ON L4K 3C7 Attn.: Anisa Kazi, 416-326-9136	Ontario Ministry of Health and Long-Term Care OGPMSS Supply Chain and Facilities Branch 99 Adesso Drive Concord, ON L4K 3C7 Attn: Amy Zhang, 416-327-0831
Prince Edward Island	Provincial Pharmacy	Provincial Pharmacy

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	P.O. Box 2000 16 Fitzroy Street Charlottetown, PEI, C1A 7N8 Att: Betty MacDonald, 902-368-4902	P.O. Box 2000 16 Fitzroy Street Charlottetown, PEI, C1A 7N8 blamacdonald@ihis.org
Saskatchewan	Saskatchewan Disease Control Laboratory Vaccine Management 5 Research Drive Regina, SK S4S 0A4 Attn: Julie Zerr, 306-787-0415	Saskatchewan Disease Control Laboratory Vaccine Management 5 Research Drive Regina, SK S4S 0A4 Attn: Julie Zerr, 306-787-0415
Yukon	Whitehorse General Hospital 5 Hospital Road Whitehorse, YT, Y1A 3H7 Att: Ken Crawford, 867-393-8790	Whitehorse General Hospital 5 Hospital Road Whitehorse, YT Y1A 3H7 Attn: Corinne Delaire, Finance

ANNEX D to PART 5 - BID SOLICITATION FEDERAL CONTRACTORS PROGRAM FOR EMPLOYMENT EQUITY - CERTIFICATION

I, the Bidder, by submitting the present information to the Contracting Authority, certify that the information provided is true as of the date indicated below. The certifications provided to Canada are subject to verification at all times. I understand that Canada will declare a bid non-responsive, or will declare a contractor in default, if a certification is found to be untrue, whether during the bid evaluation period or during the contract period. Canada will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply with any request or requirement imposed by Canada may render the bid non-responsive or constitute a default under the Contract.

For further information on the Federal Contractors Program for Employment Equity visit Employment and Social Development Canada (ESDC) - Labour website.

Date : _____ (YYYY/MM/DD) (If left blank, the date will be deemed to be the bid solicitation closing date.)

Complete both A and B.

A. Check only one of the following:

- ☐ A1. The Bidder certifies having no work force in Canada.
- ☐ A2. The Bidder certifies being a public sector employer.
- ☐ A3. The Bidder certifies being a federally regulated employer being subject to the *Employment Equity Act*.
- ☐ A4. The Bidder certifies having a combined work force in Canada of less than 100 permanent full-time and/or permanent part-time employees.

A5. The Bidder has a combined workforce in Canada of 100 or more employees; and

- ☐ A5.1. The Bidder certifies already having a valid and current Agreement to Implement Employment Equity (AIEE) in place with ESDC-Labour.

OR

- ☐ A5.2. The Bidder certifies having submitted the Agreement to Implement Employment Equity (LAB1168) to ESDC-Labour. As this is a condition to contract award, proceed to completing the form Agreement to Implement Employment Equity (LAB1168), duly signing it, and transmit it to ESDC-Labour.

B. Check only one of the following:

- ☐ B1. The Bidder is not a Joint Venture.

OR

- ☐ B2. The Bidder is a Joint Venture and each member of the Joint Venture must provide the Contracting Authority with a completed annex Federal Contractors Program for Employment Equity - Certification. (Refer to the Joint Venture section of the Standard Instructions)

FORM 1 - BID SUBMISSION		
Bidder's full legal name		
Bidder's Address		
Bidder's Procurement Business Number (PBN)		
Province in Canada the Bidder wishes to be the legal jurisdiction applicable to any resulting Contract (if other than as specified in solicitation)		
Contractor Representative – General enquiries	Name	
	Title	
	Telephone #	
	Facsimile #	
	E-mail	
Contractor Representative – Delivery follow-up	Name	
	Title	
	Telephone #	
	Facsimile #	
	E-mail	
Returns	Address to return product	
	Contact Name	
	Telephone #	
	Facsimile #	
	E-mail	
	Manufacturing	
	Shipping	
Point of Manufacturing/Shipping		
Contractor's Bid Dated		

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FORM 1 - BID SUBMISSION

Bidders who are incorporated, including those bidding as a joint venture, must provide a complete list of names of all individuals who are currently directors of the Bidder. Bidders bidding as sole proprietorship, including those bidding as a joint venture, must provide the name of the owner.

On behalf of the Bidder, by signing below, I further confirm that I have read the entire bid solicitation including the documents incorporated by reference into the bid solicitation and:

1. The Bidder considers itself and its Products able to meet all the mandatory requirements described in the bid solicitation;
2. This Bid is valid for the period requested in the bid solicitation;
3. All the information provided in the bid is complete, true and accurate; and
4. If the Bidder is issued a Contract, it will accept all the terms and conditions set out in the resulting contract included in the bid solicitation.

Signature of Authorized Representative of Bidder

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