



**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

<b>Title - Sujet</b> Fentanyl Citrate Oral Trans Mucosal	
<b>Solicitation No. - N° de l'invitation</b> W6369-17AD60/A	<b>Date</b> 2017-03-15
<b>Client Reference No. - N° de référence du client</b> W6369-17AD60	
<b>GETS Reference No. - N° de référence de SEAG</b> PW-\$\$PH-884-72699	
<b>File No. - N° de dossier</b> ph884.W6369-17AD60	<b>CCC No./N° CCC - FMS No./N° VME</b>
<b>Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2017-04-07</b>	<b>Time Zone Fuseau horaire</b> Eastern Daylight Saving Time EDT
<b>F.O.B. - F.A.B.</b> Specified Herein - Précisé dans les présentes <b>Plant-Usine:</b> <input type="checkbox"/> <b>Destination:</b> <input type="checkbox"/> <b>Other-Autre:</b> <input checked="" type="checkbox"/>	
<b>Address Enquiries to: - Adresser toutes questions à:</b> Joy(ph884), Sharon	<b>Buyer Id - Id de l'acheteur</b> ph884
<b>Telephone No. - N° de téléphone</b> (819) 420-2964 ( )	<b>FAX No. - N° de FAX</b> ( ) -
<b>Destination - of Goods, Services, and Construction:</b> <b>Destination - des biens, services et construction:</b> DEPARTMENT OF NATIONAL DEFENCE 105 Montgomery Rd BLDG BB-104 Canadian Forces Base Petawawa PETAWAWA Ontario K8H2X3 Canada	

**Instructions: See Herein**

**Instructions: Voir aux présentes**

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

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Solicitation No. - N de l'invitation  
W6369-17AD60/A

Amd. No. - N de la modif.

Buyer ID - Id de l'acheteur  
ph884

Client Ref. No. - N de rf. du client  
W6369-17AD60

File No. - N du dossier  
ph884W6369-17SD60

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**Forms:** Form 1 Bid Submission

**TITLE: Fentanyl Citrate transmucosal lozenges**

**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 Agreement on Internal Trade (AIT).

**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 (2016-04-04) 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: sixty (60) days

Insert: one hundred and eighty (180) days

**2.1.1 SACC Manual Clauses**

- (a) B4024T (2006-08-15), No Substitute Products

**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 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.

## **2.4 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.

## **2.5 Canada's Special Access Program Requirements**

Prior to a contract award, this drug requires Canada to seek authorization for importation into Canada via a Letter of Authorization (LoA) through Health Canada's Special Access Program (SAP). Contract award is contingent on Canada successfully obtaining a Letter of Authorization from Health Canada. If and when a request for a drug is authorized, the LoA is faxed directly to the Contractor/manufacturer by Health Canada.

# **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

If there is a discrepancy between the wording of the soft copy and the hard copy, the wording of the hard copy will have priority over the wording of the soft copy.

(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) **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.

#### 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. of Canada and Provincial and Territorial jurisdictions will evaluate the bids.

## 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.

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#### **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. The evaluated price for each item will be calculated as follows:

[Year 1 Unit Price x firm quantity] + [Year 1 Unit Price x Option Quantity] + [Year 2 Unit Price x Option Quantity] + [Year 3 Unit Price x Option Quantity] + [Year 4 Unit Price x Option Quantity]

#### **4.2 Basis of Selection**

A bid must comply with all requirements of the bid solicitation to be declared responsive. The responsive bid with the lowest evaluated price will be recommended for award of a contract.

### **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 Ineligibility and Suspension Policy (<http://www.tpsgc-pwgsc.gc.ca/ci-if/politiquepolicy-eng.html>), the Bidder must provide with its bid the required documentation, as applicable, 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**

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In accordance with 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 ([http://www.esdc.gc.ca/en/jobs/workplace/human\\_rights/employment\\_equity/federal\\_contractor\\_program.page?&\\_ga=1.229006812.1158694905.1413548969](http://www.esdc.gc.ca/en/jobs/workplace/human_rights/employment_equity/federal_contractor_program.page?&_ga=1.229006812.1158694905.1413548969)).
- (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.

## **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 the Identified User 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
- (iii) Partial replacement and partial reimbursement or partial credit.

## **6.4 Term of Contract**

### **6.4.1 Period of Contract**

The period for placing orders and rendering services against the Contract will be from contract award up to and including March 31, 2021.

### **6.4.2 Optional Goods and/or Services**

- (a) The Contractor grants to Canada an irrevocable option to purchase additional quantities of the goods, services or both as described at Annex B up to a maximum of 134 boxes under the same conditions and at the prices stated in the Contract. This option is conditional upon Canada obtaining a Letter of Authorization through Health Canada's Special Access Program prior to any amendment being issued. The option may only be exercised by the Contracting Authority and will be evidenced, for administrative purposes only, through a contract amendment
- (b) The Contracting Authority may exercise the option at any time before the expiry of the Contract by sending a written notice to the Contractor.
- (c) More than one amendment may be issued to exercise this option. The minimum number of boxes to be ordered for each amendment is 34 boxes.
- (d) Nothing contained in this Contract will require Canada to exercise the option and the exercise of the option is at the sole discretion of Canada.

## **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) 430-2964  
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

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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 Identified User is provided in Annex C.
- (b) The Identified User is the representatives of the department, agency, province or territory for whom the Work is being carried out under the Contract. The Identified User 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 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 Delivery

### 6.6.1 Delivery Required - Firm Quantity (item 001)

All firm deliverables under any resulting contract are requested complete by August 15, 2017.

### 6.6.2 Delivery - Option Quantities (item 002)

Delivery for any option quantity will be within \_\_\_\_\_ days/ weeks of a contract amendment (to be filled in by Bidder)

### 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:

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- (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 Contract and delivered DDU Delivered Duty UnPaid (, 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.

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- (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 "Certification 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 Shipment of Dangerous Goods / Hazardous Products**

The Contractor must label and ship goods falling within the Hazardous Products Act, R.S.C. 1985, c. H-3 and regulation(s) in accordance with the said Act and regulation(s) accompanied by the required material safety data sheet(s) completed in either English or French. The label must clearly identify the contents of the hazardous material and the material safety data sheet must explain what those hazards are.

### **6.7 Payment**

#### **6.7.1 Basis of Payment - Firm Unit Price**

In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid a firm unit price as specified in Annex B. Customs duties are excluded and Applicable Taxes are extra.

#### **6.7.2 SACC Manual Clauses**

- (a) C6000C (2011-05-16), 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 the 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 24 months remaining on the date of delivery.

## **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) Contractor's Return 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.

## **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 Canada's Special Access Program**

- (a) As required by Health Canada's Special Access Program in order to facilitate importation/shipment, the Contractor must include the following label on the shipping container: "URGENT-EMERGENCY DRUG", and must include a copy of the following document:

-Letter of Authorization Issued by Health Canada's Special Access Program.

- (b) For Schedule II narcotics under the United States *Controlled Substances Act* (DEA Number 9801), and for Schedule I controlled drugs as per *Canada's Controlled Drugs and Substances Act* (1996, c. 19), Part VII, Schedule I, Section 16: "Fentanyl, its salts, derivatives, and analogues and salts of derivatives and analogues..." the shipment must also include copies of the following documents:

-Export Permit issued by the United States Drug Enforcement Agency; and  
-Import Permit issued by Health Canada's Office of Controlled Substances.

## **6.15 Certifications**

### **6.15.1 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 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.

## **6.17 Priority of Documents**

If there is a discrepancy between the wordings 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);
- (c) Annex A: Requirement;
- (d) Annex B: Basis of Payment;
- (e) Annex C: Identified Users and Delivery Points;
- (f) the Contractor's bid dated \_\_\_\_\_

## **6.18 Defence Contract**

- (a) The Contract is a defence contract within the meaning of the Defence Production Act, R.S.C. 1985, c. D-1, and must be governed accordingly.
- (b) Title to the Work or to any materials, parts, work-in-process or finished work must belong to Canada free and clear of all claims, liens, attachments, charges or encumbrances. Canada is entitled, at any time, to remove, sell or dispose of the Work or any part of the Work in accordance with section 20 of the Defence Production Act.

## **6.19 Insurance**

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

## **Annex A**

### **STATEMENT OF REQUIREMENT, PRICING AND DELIVERABLES**

#### **1. Scope**

The Contractor must supply fentanyl citrate trans mucosal lozenges 800mcg.

#### **2. Quantity**

See Annex B - Basis of Payment



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**W6369-17AD60/A**

Amd. No. - N de la modif.

Buyer ID - Id de l'acheteur  
**ph884**

Client Ref. No. - N de rf. du client  
VME

File No. - N du dossier

CCC No/N CCC - FMS No/ N

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## **ANNEX B**

### **BASIS OF PAYMENT**

#### **1. Pricing Information**

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

#### **Item 001 – Firm Quantity**

Item	Year	Firm Quantity	Unit of Issue	Firm Unit Price CDN\$ (DDU Identified user)
<b>001</b>	Contract award - March 31, 2021	100 boxes of 30 (3,000 eaches)	Box of 30	\$_____ per box

#### **Item 002 – Option Quantity**

Item	Option Quantity	Firm Unit Price CDN\$ Year 1 April 1, 2017-March 31, 2018 (DDU Identified User)	Firm Unit Price \$CDN Year 2 April 1, 2018-March 31, 2019 (DDU Identified User)	Firm Unit Price CDN\$ Year 3 April 1, 2019-March 31, 2020 (DDU Identified User)	Firm Unit Price CDN\$ Year 4 April 1, 2020-March 31, 2021 (DDU Identified User)
<b>002</b>	Up to a maximum of 134 boxes (or 4,020 eaches)	\$_____ per box	\$_____ per box	\$_____ per box	\$_____ per box

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ph884

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## **ANNEX C**

### **IDENTIFIED USER AND DELIVERY POINT**

#### **Billing address**

Department of National Defence  
Canadian Forces Base Petawawa  
101 Colonel By Drive  
Ottawa, Ontario  
Canada  
K1A 0K2  
Attn: Wendy Dowe, D Svcs C 3-4-3

#### **Shipping Address**

Department of National Defence  
Canadian Forces Base Petawawa  
Central Medical Equipment Depot  
105 Montgomery Blvd. BB104  
Petawawa, Ontario  
Canada  
K2H 2X3

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

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<b>Contractor's Bid Dated</b>	
<b>FORM 1 - BID SUBMISSION</b>	
<b>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.</b>	
<p>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:</p> <ol style="list-style-type: none"><li>1. The Bidder considers itself and its Products able to meet all the mandatory requirements described in the bid solicitation;</li><li>2. This Bid is valid for the period requested in the bid solicitation;</li><li>3. All the information provided in the bid is complete, true and accurate; and</li><li>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.</li></ol>	
<b>Signature of Authorized Representative of Bidder</b>	