

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 0A1 / Noyau 0A1
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

Title - Sujet FENTANYL TRANSMUCOSAL LOZENGES	
Solicitation No. - N° de l'invitation W3931-140029/A	Date 2013-06-28
Client Reference No. - N° de référence du client W3931-140029	
GETS Reference No. - N° de référence de SEAG PW-\$\$PH-884-62994	
File No. - N° de dossier ph884.W3931-140029	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2013-07-17	
Time Zone Fuseau horaire Eastern Daylight Saving Time EDT	
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) 956-6510 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction: Specified Herein Précisé dans les présentes	

Instructions: See Herein

Instructions: Voir aux présentes

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

Delivery Required - Livraison exigée See Herein	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

PART 1 - GENERAL INFORMATION

1. Security Requirement

There is no security requirement associated with this bid solicitation.

2. Requirement

To supply 2,520 fentanyl citrate transmucosal lozenges 800mcg as described at Annex A.

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 of receipt of notification that their bid was unsuccessful. The debriefing may be provided in writing, by telephone or in person.

PART 2 - BIDDER INSTRUCTIONS

1. Standard Instructions, Clauses and Conditions

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 issued by Public Works and Government Services Canada.

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.

The 2003 (2013-06-01) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

2. Submission of Bids

Bids must be submitted only to Public Works and Government Services Canada (PWGSC) **Bid Receiving Unit** by the date, time and place indicated on **page 1** of the bid solicitation.

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 questions or may request that the Bidder do so, so that the proprietary nature of the question is eliminated, and the enquiry can be answered with copies to all bidders. Enquiries not submitted in a form that can be distributed to all bidders may not be answered by Canada.

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

1. Bid Preparation Instructions

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

Section I: Technical Bid 1 hard copy

Section II: Financial Bid 1 hard copy

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.

Canada requests that bidders follow the format instructions described below in the preparation of their bid:

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

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:

- 1) 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
- 2) 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.

Section I: Technical Bid

In their technical bid, bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.

The Bidder is required to provide full details on its policy for exchanges / credits for returned merchandise, including the return of expired or damaged products, and the return of pharmaceuticals for destruction.

Section II: Financial Bid

Bidders must submit their financial bid in accordance with the Basis of Payment.

1.1 Exchange Rate Fluctuation

C3011T (2010-01-11) - Exchange Rate Fluctuation

Section III: Certifications

Bidders must submit the certifications required under Part 5

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION**1. Evaluation Procedures**

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

1.2 An evaluation team composed of representatives of Canada will evaluate the bids.

2. Basis of Selection

A bid must comply with all the 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.

Ranking will be established using the firm quantities for all items, plus 100% of the option quantities.

PART 5 - CERTIFICATIONS

Bidders must provide the required certifications and related documentation to be awarded a contract. Canada will declare a bid non-responsive if the required certifications and related documentation are not completed and submitted as requested.

Compliance with the certifications bidders provide to Canada is subject to verification by Canada during the bid evaluation period (before award of a contract) and after award of a contract. The Contracting Authority will have the right to ask for additional information to verify the bidders' compliance with the certifications before award of a contract. The bid will be declared non-responsive if any certification made by the Bidder is untrue, whether made knowingly or unknowingly. Failure to comply with the certifications, to provide related documentation or to comply with the request of the Contracting Authority for additional information will also render the bid non-responsive.

1. Mandatory Certifications Required Precedent to Contract Award**1.1 Code of Conduct and Certifications - Related documentation**

By submitting a bid, the Bidder certifies that the Bidder and its affiliates are, in compliance with the provisions as stated in Section 01 Code of Conduct and Certifications - Bid of Standard Instructions 2003 . The related documentation therein required will assist Canada in confirming that the certifications are true.

1.2 Federal Contractors Program for Employment Equity - Bid Certification

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 (<http://www.hrsdc.gc.ca/eng/labour/index.shtml>) available from Human Resources and Skills Development Canada (HRSDC) - Labour's website.

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

1. Security Requirement

There is no security requirement applicable to this Contract.

2. Requirement

The Contractor must provide 2,520 fentanyl citrate transmucosal lozenges 800mcg in accordance with the Requirement at Annex A..

2.1 Product Dating

All product supplied must have a shelf life of **no less than 24 months** remaining on the date of delivery.

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 issued by Public Works and Government Services Canada.

3.1 General Conditions

2010A (2013-04-25) General Conditions - Goods (Medium Complexity), apply to and form part of the Contract.

3.2 Warranty - Amendment to General Conditions 2010A

Section 09, paragraph 1, of General Conditions 2010A, which will form part of any Contract Canada may enter into, will not apply to items with a specified expiry date. The following warranty will apply instead:

Despite inspection and acceptance of the supplies 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 supplies conform to their Specifications until the expiration date required by the Requirement or by the Food and Drugs Act and Regulations. The Contractor must, upon the request of the Minister, replace as soon as possible any supplies that fail to so conform or that deteriorate prior to the said expiration date.

4. Term of Contract

4.1 Period of Contract

The period of the Contract is three years from date of Contract award.

4.2 Optional Goods

The Contractor grants to Canada the irrevocable option to acquire the optional goods described at Annex A of the Contract under the same conditions and at the prices stated in the Contract. The option may only be exercised by the Contracting Authority and will be evidenced, for administrative purposes only, through a contract amendment. More than one amendment may be issued to exercise this option.

4.3 Options -- Right to Exercise

The options outlined above will remain valid and open for exercise by Canada, in whole or in part, at the discretion of Canada, during the period of the Contract. Exercise of these options will be by written notice, or written notices, from Canada prior to the expiry date of the Contract.

Nothing in the Contract obligates Canada to exercise these options, in whole or in part, and the exercise of these options will be at the sole discretion of Canada.

4.4 Delivery

4.4.1 Delivery Required - Firm Quantity

All firm deliverables under any resulting contract are requested complete on or before October 21 2013.

4.4.2 Delivery of the Option Quantities:

Delivery of any option quantity will be completed within _____ days/weeks of contract amendment. (please fill in)

4.5 Packaging

All shipments of goods under this contract must clearly indicate on packing slips and on the outside of outer packages/cartons, the following:

- Contractor's Name
- Manufacturer's Brand Name
- Lot Number
- Expiry Date

Additionally, each package, carton, vial, ampoule, bottle, and pre-filled syringe (if applicable) must also clearly indicated the following:

- Drug Identification Number (DIN) and Nato Stock Number (NSN) (if applicable)
- Lot Number
- Expiry Date of Shelf Life

The Contractor must indicate the carton(s) which contain the packing slip.

The Contractor must clearly identify partly packed carton(s)/box(es).

Goods must be delivered on 40" x 48" pallets and be securely bound, or must be delivered in accordance with other specific directions as provided by a Identified User.

Packaging is to be in accordance with good commercial standards to ensure safe arrival at destination. The Contractor will be required to use the utmost care in ensuring that all goods is properly labeled and packaged in compliance with the BGTD Regulations.

4.6 Canada's Special Access Program

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

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

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, their salts, derivatives, and analogues and salts of derivatives and analogues,..."", this 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.

4.7 Shipping Instructions - Delivery at Destination

1. Goods must be consigned to the destination specified in the Contract and delivered DDU Delivered Duty Unpaid Petawawa Ontario, Incoterms 2000 for shipments from a commercial contractor.

2. The Contractor is responsible for the risk of transport. The Canadian Department of National Defence will be responsible for all administration and customs clearance, including the payment of customs duties and taxes.

5. Authorities

5.1 Contracting Authority

The Contracting Authority for this Contract is:

Sharon Joy
Supply Specialist; Drugs, Vaccines and Biologics Division
Public Works and Government Services Canada
Tel: (819) 956-6510 Fax: (819) 956-7340
Place du Portage, Phase III, 6B3
Gatineau, PQ, K1A 0S5
sharon.joy@pwgsc.gc.ca

The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. 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.

5.2 Technical Authority

The Technical Authority for the Contract is:

Major Richard Quinlan
J4 Med Ops & Plans
Canadian Forces Health Services Group

Telephone :613-945-6998
E-mail address: richard.quinlan@forces.gc.ca

The Technical Authority is the representative of the department or agency for whom the Work is being carried out under the Contract and is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Technical Authority, however the Technical Authority has 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.

5.3 Contractor's Representative

Name and telephone number of the person responsible for :

General enquiries

Name: _____

Telephone No.: _____

Facsimile No.: _____

E-mail address: _____

Delivery follow-up

Name: _____

Telephone No.: _____

Facsimile No.: _____

E-mail address: _____

6. Payment

6.1 Basis of Payment - Firm 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 the contract. Customs duties are excluded if applicable, and Applicable Taxes are zero-rated.

6.2 SACC Manual Clauses

SACC Manual Clause C6000C (2011-05-16), Limitation of Price

SACC Manual Clause G1005C (2008-05-12), Insurance

6.3 Multiple Payments

Canada will pay the Contractor upon completion and delivery of units in accordance with the payment provisions of the Contract if:

- (a) an accurate and complete invoice and any other documents required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
- (b) all such documents have been verified by Canada;
- (c) the Work delivered has been accepted by Canada.

7. Invoicing Instructions

1. 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.

2. Invoices must be distributed as follows:

- (a) The original and one (1) copy must be forwarded to the address shown on page 1 of the Contract for certification and payment.
- (b) One (1) copy must be forwarded to the Contracting Authority identified under the section entitled "Authorities" of the Contract.

8. Certifications

8.1 Compliance

Compliance with the certifications and related documentation provided by the Contractor in its bid is a condition of the Contract and subject to verification by Canada during the term of the Contract. If the Contractor does not comply with any certification, provide the related documentation or if it is determined that any certification made by the Contractor in its bid is untrue, whether made knowingly or unknowingly, Canada has the right, pursuant to the default provision of the Contract, to terminate the Contract for default.

9. 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.

10. 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) 2010A (2013-04-25) General Conditions - Goods (Medium Complexity);
- (c) Annex A, Statement of Requirement, pricing and Deliverables;
- (d) the Contractor's bid dated _____ (to be inserted at contrat award)

11. Defence Contract

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.

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*.

12. Product Specific Clauses

12.1 Point of Manufacturing/Shipping

State point of manufacture/shipping of goods:

Solicitation No. - N° de l'invitation

W3931-140029/A

Amd. No. - N° de la modif.

File No. - N° du dossier

ph884W3931-140029

Buyer ID - Id de l'acheteur

ph884

CCC No./N° CCC - FMS No/ N° VME

W3931-140029

Manufacturing: _____

Shipping: _____

12.2 Adverse Drug Event Reporting Requirement

The Contractor understands and agrees that it must comply with all Federal/Provincial/Territorial adverse drug reaction reporting requirements.

12.3 Product Recall and/or Withdrawal

In the event of a product recall or a withdrawal, the Contractor will be responsible for notifying Canada, for collecting and destroying the recalled or withdrawn product, and for providing Canada with full refund for the recalled or withdrawn product.

Annex A
STATEMENT OF REQUIREMENT, PRICING AND DELIVERABLES

- 1. Requirement:** To supply Canada's Department of National Defence with 2,520 Fentanyl Citrate transmucosal 800mcg lozenges, on plastic handles, to be delivered in accordance with the schedule listed in Section 4.4 , entitled *Delivery*.

Delivery Address:

Department of National Defence
Central Medical Equipment Depot
Building BB104
105 Montgomery Road
Petawawa, Ontario
Canada K8H 2X3
Attn: Receiving

2. Price Proposal

All prices must be in US dollars, DDU Delivered Duty Unpaid (Petawawa, Ontario Canada), transportation charges included, custom and duties excluded, if applicable; and where applicable, zero-rated for Goods and Services Tax (GST) or Harmonized Sales Tax (HST).

Item	Description	Firm Quantity	Unit of Issue	Price per unit of issue (\$USD)
1	FIRM QUANTITY Fentanyl Citrate transmucosal 800 mcg lozenges, on a plastic handle. NSN: <u>6505-CF-002-1960</u>	2,520 eaches	_____	\$_____ (\$USD)

Item	Description	Option Quantity	Unit of Issue (ie per box)	Price per unit of issue (\$USD)
2	OPTION QUANTITY Fentanyl Citrate transmucosal 800 mcg lozenges, on a plastic handle. NSN: <u>6505-CF-002-1960</u>	5,040 eaches	_____	\$_____ (\$USD)