Health Canada Santé Canada

Green Alert - Duplex printing of this document will save paper

REQUEST FOR STANDING OFFER (RFSO)

Reference Number: 1000201293

CLOSING DATE: June 19, 2018 **CLOSING TIME & ZONE: 2:00 PM, EDT**

PROJECT TITLE: **Standing Offer Agreement for the provision of scientific expert advice or review and recommendation on non-clinical and Toxicology data.**

Branch/ Directorate Health Products and Food Branch (HPFB), Therapeutic Products Directorate (TPD) Health Canada

NOTE: Bid Submission Envelopes are to be delivered "only" to the following address:

Health Canada Bid Receiving Unit **Hours of Operation:** 07h30 to 16h30 (EDT)
Federal Records Centre Building,
161 Goldenrod Driveway, Address Locator 1801B
Ottawa, Ontario K1A 0K9
Attention: Randy Brown
RFSO Reference Number: 1000201293

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

Name: Randy Brown
Senior Procurement and Contracting Officer
e-mail:randy.brown2@canada.ca

RFSO Issue Date: May 11, 2018

TABLE OF CONTENTS

PART I STATEMENT of WORK

1.0 Scope

1. 1 Title

Standing Offer Agreement(s) for the provision of scientific expert advice or review and recommendation on non-clinical and toxicology data.

1.2 Introduction

The Therapeutic Products Directorate (TPD) at Health Canada (HC) requires the services of external scientific experts to provide scientific advice and/or review non-clinical data, concerns/issues on multiple different ongoing files for new drug submissions or supplemental new drug submissions.

The assessment will guide TPD in determining the final disposition of these submissions and any further evaluation of the product.

1.3 Objectives of the Requirement

On an as and when required basis provide scientific expert advice or review and recommendation on non-clinical data (e.g., pharmacology, non-clinical pharmacokinetics, toxicology, genotoxicity) and/or issues including those related to qualifying data for impurities, safe use of the product based on the level of the inactive ingredient(s) in the drug products on selected drug submissions filed by Pharmaceutical Companies, as identified by the Therapeutic Products Directorate (TPD), Health Canada (HC).

The Contractor shall perform the review of the information provided, verify the validity of the sponsor's conclusions and/or identify deficiencies in the data, and provide recommendations in the form of a written report. The report will also include the contractor's expert advice/comments in regard to the material provided.

Expertise in toxicology is required to evaluate the submission. Knowledge of the International Conference on Harmonization (ICH) guidelines and other relevant guidelines on review of non-clinical data and the statistical analyses thereof is essential. Link: www.ich.org.

1.4 Definition of a Standing Offer Agreement (SOA)

A Standing Offer Agreement (SOA) is not a Contract. It is an offer from a supplier to provide services on a prearranged pricing basis and under set terms and conditions for a specified period of time on an as-and-when requested basis. A separate Contract is entered into each time a “Call-up” is made against a SOA. Such Call-ups are made in accordance with the provisions of the SOA. The Crown’s liability shall be limited to the actual value of the Call-ups made within the period specified in the SOA

1.5 Estimated Value and Duration of the Requirement

1.5.1 The total estimated value of all Standing Offer Agreements combined resulting from this Request for Standing Offer (RFSO), including option years, shall not exceed $2,500,000.00 (CAD). It is estimated that Health Canada will spend approximately $1,000,000.00 for the initial two (2) year period. At the sole discretion of Health Canada, this Standing Offer

Agreement may be renewed by up to three (3) additional one (1) year periods for a combined value not to exceed $1,500,000.00.

1.5.2 Individual Call-ups against each Standing Offer Agreement must not exceed a total of **$80,000** (including applicable taxes).

1.6 Background, Assumptions and Specific Scope of the Requirement

The services of an external expert toxicologist will be used on an as and when required basis to provide more flexibility for TPD to meet the service standards for the review of drug submissions.

For each file to be reviewed, including provision of expert advice when needed, the estimated time allocated for the work to be done will be specified prior to initiating the work. The detail of the work to be completed will be agreed upon in writing between the Project Authority and the contractor.

1.7 Allocation of Work

Health Canada, will award Standing Offer Agreement(s) (SOA's) to all qualified bidders. The work is to provide independent scientific external expertise on an as and when required basis by the issuance of the Call-up Document.

Bidders must be compliant with the requirements of this Request for Standing Offer (RFSO), as indicated in Part III, *Bid Selection Process.* The work under any SOA will be allocated in the following manner.

The Project/Technical Authority may award a Call-up to the Contractor who, in HC's exclusive opinion, can best render the required service, based on the following factors:

a) current, valid security screening level of the Contractor/firm;
b) availability of the Contractor;
c) Conflict of Interest Form (Appendix "C")
d) established cost to complete the work.

1.8 Call-Up Procedures

1.8.1 Call-ups under this Standing Offer Agreement will be subject to the terms and conditions of this RFSO.

1.8.2 In accordance with the allocation of work for this Standing Offer Agreement (Section 1.7, *Allocation of Work*), when services identified in this RFSO are required, Health Canada will initiate the Call-up process, by forwarding a Contractor a Statement of Work (list of submission numbers) via email to a supplier.

1.8.3 The SOA holder shall acknowledge receipt of the Call-up document and respond within two (2) business days of receipt.

1.8.4 It is understood and agreed that the Standing Offer holder shall not commence any work until authorized in writing by Call-up issued by the Health Canada Project Authority or his/her delegate.

1.8.5 No costs incurred before receipt of a signed "Call-up Against a Standing Offer" from the Health Canada Project Authority, can be charged to any resulting SOA.

1.9 Cancellation of a Call-up

Health Canada reserves the right to cancel a Call-up at their discretion, and will only reimburse any costs incurred at that point that can be substantiated by proper documentation.

1.10 Limitation of the Standing Offer Agreement

For the duration of the SOA, the Standing Offer Holder agrees to notify in writing the Departmental Representative of his/her desire to withdraw from the SOA at a minimum of thirty (30) days prior to ceasing any provision of the services agreed to within the SOA.

Should the Standing Offer Holder default on any Call-Up issued, HC may, by notice to the Standing Offer Holder, terminate the whole or any part of the work. The Standing Offer Holder shall be liable to Her Majesty for any excess costs relating to the completion of the work.

2.0 Requirements

2.1 Tasks, Activities, Deliverables and Milestones

1. The Contractor shall perform a critical review (evidence based), in the form of a written report, for the material provided. A summary of the key findings in the data reviewed also needs to be a part of the report. The format of the report to be used is that of the Pharmaceutical Safety and Efficacy Assessment Template (PSEAT) (Please refer to Section 2.2 also).

2. The contractor shall apply personal expertise and consult up-to-date literature and/or other experts on non-proprietary medical/scientific issues, as necessary, to execute the tasks identified in the Table 2.1 below. The report will thus include the contractor's expert advice/ comments in regard to the material provided.

3. The contractor will have to formulate and forward any questions or clarifications for the sponsor to the Project Authority. These questions and appropriate analysis of the responses by the contractor should also be a part of the contractor's report in the appropriate section of the PSEAT.

4. Finally, the contractor may be called upon to discuss and provide scientific expert advice to help HC in its assessment of the risk-benefit of products under review.

2.1.1 To perform a critical review and provide expert scientific opinion, in the form of feedback or a written report, on issues including, but not limited to, the following:

- non-clinical data (e.g., pharmacology, non-clinical pharmacokinetics, toxicology, genotoxicity);
- responses to clarifaxes from sponsors that may require special toxicology or non-clinical expertise;
- appropriate safety levels of excipient ingredients identified in drug substances for ongoing drug submissions;
- qualifying data and studies for impurities identified during chemistry review of drug submissions;

- effect of shelf-life extensions on levels of impurities in drug substances for ongoing drug submissions;

Table 2.1 Tasks, Activities, Deliverables and Milestones (Work Breakdown Structure) for Review Related Tasks:

TASK "As and when required basis"	DELIVERABLE "As and when required basis"	LEVEL OF EFFORT	DUE DATE	HC REVIEW
1. Preparation	The consultant will read briefing package(s) forwarded by the HC review bureau.	Up to 1-2 hrs.	TBD	N/A
2. To review the information provided and submit a written draft report (see 2.1) to the HC Project Authority for review and comments.	First draft report of the review (electronic copy) of the studies specified by HC (refer to 2.1.1), including clarifications requested from the sponsor and associated responses.	Will depend on the activity assigned by the Project Authority and will be determined at the time of work to be carried out.	Will be determined at the time of work to be carried out.	Up to 5 days from receipt of draft report to review and provide comments.
3. Teleconferences	The consultant will make him/herself available for teleconferences with the HC review bureau.	Up to 1.5 hrs per teleconference call.	To be scheduled on an as-needed basis by the Project Authority.	
2. The consultant will make the appropriate revisions of the draft report based on HC comments. The final revision will be sent to the HC Project Authority.	Revised report	Will depend on the activity assigned and will be determined at the time of work to be carried out.	Will be determined at the time of work to be carried out.	Review of the revised report within up to 3 business days.
TOTAL = up to 450 hours				

2.2 Specifications and Standards

All written reports will be submitted to the appropriate Project Authority.

These written reports must adhere to the following guidelines:

- Electronic Format: Microsoft Office Word using the Product Safety and Efficacy Assessment Template (using relevant section of the appropriate section of PSEAT);
- All recommendations and/or opinions must be evidence based, and represent an objective critical analysis that is presented in a concise, logical manner using appropriate scientific terminology;
- Must comply with guidelines, including ICH, as well as any applicable TPD Standard Operating Procedures (SOPs) (as provided to the contractor by TPD).

2.3 Technical, Operational and Organizational Environment

Strict confidentiality must be upheld in order to protect trade secrets and patient privacy.

The work will be performed on the Contractor's site. The Standing Offer Holder(s) are expected to be in contact with the HC Project Authority on occasion on an as needed basis

2.4 Method and Source of Acceptance

All deliverables and services rendered under the SOA Call-up are subject to inspection by the Project Authority or a designated representative. Should any service or deliverable not be to the satisfaction of the Project Authority, as submitted, the Project Authority will reserve the right to reject it or require correction before payment will be authorized.

Where specifically required to do so by Health Canada, the Contractor must provide the services of the personnel named in the proposal to perform the work, unless the Contractor is unable to do so for reasons beyond his/her control.

Should any of the Contractor's personnel at any time be unable to provide services, the Contractor shall be responsible for providing replacement personnel at the same cost who shall be of same or greater ability and attainment, and whom shall be acceptable and authorized by the Project Authority. Under no circumstance shall the Contractor allow the performance of services by a replacement resource that has not been authorized by the Project Authority.

2.5 Reporting Requirements

The contractor will provide written draft and final reports and participate in teleconferences as required for each task scheduled in Section 2.1.

2.6 Contractor Project Management Control Procedures

The Health Canada individual identified in the Call-up as the HC Project Authority will ensure the contract will be brought in on time, on budget and is of an acceptable quality.

2.7 Change Management Procedures

Health Canada does not anticipate any changes to the requirements detailed in this RFSO. However, if changes do arise they must be done in writing by the HC Project Authority, and an amendment must be prepared to reflect these changes.

2.8 Ownership of Intellectual Property

The Crown will own the Copyright of all the Intellectual Property (IP) produced in any SOA signed by the contractor as a result of this RFSO. Health Canada has determined that any intellectual property arising from the performance of the work under the contract will vest in Canada, as per Section 6.5 of the Treasury Board Policy on Title to Intellectual Property Arising Under a Crown Procurement Contract which states that the Crown may retain ownership of the intellectual property: "Where the Foreground consists of material subject to copyright with the exception of computer software and all documentation pertaining to that software."

2.9 Applicable Law

The Standing Offer Agreements (s) and any resultant Call-ups shall be interpreted and governed, and the relations between the Parties, determined by the laws in force in 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 Canadian province or territory specified and inserting the Canadian province or territory of their choice. If no change is made, it acknowledges the applicable law specified is acceptable to the bidder.

3.0 Other Terms and Conditions of the SOW

3.1 Authorities

Names will be provided in each Call-up.

Departmental Representative:

Identified in the Articles of Agreement between the Crown and the Contractor, the Departmental Representative is the officer or employee of the Crown who is authorized by the Minister to perform any of the Departmental Representative's functions under the Standing Offer Agreement.

Project Authority:

Identified in each individual call-up document, the HC Project Authority or his/her delegate is responsible for all matters concerning the technical content of the work under any resulting Call-up against the SOA(s). Any proposed changes to the scope of the Call-up are to be discussed with the HC Project Authority, and confirmed by a Call-up amendment issued by the HC Project Authority.

Health Canada Administrative Contact:

The Health Canada Administrative Contact is responsible for all matters concerning the administrative and invoicing issues under any resulting Call-up against any of the SOA(s).

3.2 Health Canada's Obligations

Health Canada shall provide the following:

- access to all the referenced information
- ensure availability of staff with whom the contractor may need to consult;
- provide comments on reports;
- schedule teleconferences, if required;
- provide applicable documentation as per Section 6.1;
- provide other assistance or support;
- hardware/laptop and account access when required.

3.3 Standing Offer Holder's Obligations

Upon receipt of a duly authorized Call-up from Health Canada, the Contactor shall provide the services in accordance with the Statement of Work, and the specific delivery requirements as described in the Call-up:

- communicate to the HC Project Authority well in advance if they will not be able to complete the tasks, deliverables and milestones as identified in Section 2.1 within the time frame;
- submit all written reports in electronic Microsoft Office Word or WordPerfect;
- follow the TPD applicable guidelines and templates provided by the HC Project Authority;
- participate in teleconferences, as needed;
- maintain security clearance with no conflict of interest for the duration of the contract;
- maintain open communication (phone, e-mail, etc.) with the HC Project Authority in a timely manner;
- complete a Conflict of Interest Form, Section 3.8, Appendix "C" prior to each assigned work requirement;
- return all materials/equipment belonging to Health Canada upon completion of the SOA.

3.4 Location of Work, Work Site and Delivery Point

Due to existing workload and deadlines, all personnel assigned to any contract resulting from this RFSO must be ready to work in close and frequent contact with the Departmental Representative and other departmental personnel when needed. It is expected that the work will be performed off-site.

3.5 Language of Work

All written and oral communication will be in English.

3.6 Conflict of Interest

A separate Conflict of Interest Form (refer to Appendix "C") is to be completed by the Contractor's Resource or Individual Contractor and signed off/accepted by Health Canada prior to every Call-up being issued.

3.7 Special Requirements

The Contractor will be required to access all documentation via Health Canada's Web Office 2.0 /Citrix site and will be provided with an account. If and when needed Health Canada will provide the necessary hardware/laptop and VPN account access for connection to the Health Canada network .

Under no circumstances will the Contractor be permitted to download information to their computer/hardware. As well the Contractor will not be permitted to upload any files to a Health Canada LAN drive. Any and all data must be worked on and stored on the HC LAN drive assigned with the provided Web office account/access via a Health Canada laptop as required.

Under no circumstances can the Contractor print and/or store/file any of the information available on the HC LAN.

No other individuals/personnel in the vicinity of the Contractor's computer shall be permitted to view any of the on-line data.

3.8 Security Requirements

The Contractor/Offeror personnel requiring access to **PROTECTED** information, assets or sensitive work site(s) must **EACH** hold a valid **RELIABILITY STATUS**, granted or approved by Health Canada or CISD/PWGSC.

Subcontracts which contain security requirements are **NOT** to be awarded without the prior written permission of Health Canada.

The Contractor/Offeror must comply with the provisions of the:

(a) Security Requirements Check List and security guide (if applicable), attached at Appendix “B”;

(b) Industrial Security Manual (Latest Edition).

It is a condition that, prior to performance of any obligation under any Call-up resulting from this RFSO, the Contractor and sub-contractors and their employees assigned to the performance of such contract will be security cleared by the federal government at the reliability level.

If the successful bidder does not have the required reliability level prior to performance of any obligation under any contract resulting from this RFSO, Health Canada will sponsor the security screening for the Contractor and sub-contractors and their employees assigned to the performance of such contract until it is obtained. However, no Call-up against any Standing Offer can be permitted for that resource until the required security clearance is obtained.

3.9 Insurance Requirements

It is the sole responsibility of the Standing Offer Holder to decide whether or not any insurance coverage is necessary for its own protection or to fulfill its obligations under the SOA and to ensure compliance with required federal, provincial or municipal law. Any such insurance shall be provided and maintained by the Standing Offer Holder at its own expense.

3.10 Travel and Living Expenses

N/A

3.11 eReview Requirements:

Access to docuBridge (eReview viewing tool) may be granted to consultants in order to perform the work outlined in the "Statement of Work for Services". A one-hour web conferencing/training session on DocuBridge will be provided as required. Access to DocuBridge will be provided through the department Citrix Web Office infrastructure. Due to its technical design, Web Office access also allows for Internet access. This Internet access is intended for Health Canada employees only and is monitored on a routine basis for any unauthorized or inappropriate use. By signing any potential Standing Offer Agreement/Call Up the Contractor agrees to refrain from using Health Canada's Internet access and acknowledges that unauthorized or inappropriate use of Health Canada's Internet access may result in repercussions.

4.0 Project Schedule

4.1 Expected Start and Completion Dates

The initial period of the SOAs will be for two (2) years from date of signing of the Standing Offer Agreement(s) and include three (3) one (1) year optional periods which may be exercised at Health Canada’s discretion. The total duration of the SOA’s may be up to five (5) years.

4.2 Schedule and Estimated Level of Effort (Work Breakdown Structure)

Please refer to Section 2.1, *Tasks, Activities, Deliverables and Milestones* for work breakdown structure.

5.0 Required Resources/Types of Roles to be Performed

Contractor shall have the following background and requirements to be provided upon request:

Experience and expertise in review of non-clinical information (e.g. pharmacology, non-clinical pharmacokinetics, toxicology, genotoxicity).

6.0 Applicable Documents and Glossary

6.1 Applicable Documents

Upon contract award, HC shall provide the contractor with the PSEAT template and SOPs.

6.2 Relevant Terms, Acronyms and Glossaries

HC - Health Canada
TPD - Therapeutic Product Directorate

OPPRS -	Office of Planning, Performance & Review Services
SOW -	Statement of Work
TC -	Teleconference
N.A. -	Not-Applicable
SOP -	Standard Operating Procedure
BCANS -	Bureau of Cardiology, Allergy and Neurological Sciences
BMORS -	Bureau of Metabolism, Oncology and Reproductive Sciences
BGIVD -	Bureau of Gastroenterology, Infection and Viral Diseases
ORM -	Office of Risk Management
MD -	Medical Doctor
PSEAT -	Pharmaceutical Safety and Efficacy Assessment Template
ICH -	International Conference on Harmonization

PART II PROPOSAL REQUIREMENTS

7.0 Administrative Instructions

7.1 General Information

7.1.1 Components, Language and Number of Copies

You are invited to submit the copies of your proposal in either official language (English or French) as specified below. The RFSO Reference Number and the name of the Departmental Representative must be marked on the cover page of each document, binder and respective envelopes.

Your proposal **must** be structured in the following manner:

-one original covering letter, and 4 copies signed by an authorized representative of your firm;
-**five (5) copies** of the Technical Proposal **<u>including</u>** with each copy the **<u>signed</u>** certification Appendix "A"; and
-**two (2) copies** of the Financial Proposal, contained in a separate sealed envelope. Failure to provide the Financial Proposal in a separate sealed envelope will render your bid non-responsive.

7.1.2 Bid Validity Period

Please refer to Appendix "A" - Certifications

7.1.3 No Payment for Pre-Contract Costs

No payment shall be made for costs incurred in the preparation and submission of a proposal in response to this RFSO. No costs incurred before receipt of a signed SOA and Call-up or specified written authorization from the Departmental Representative can be charged to the proposed contract.

7.2 Delivery Instructions for Bid / Proposal

Bid submission envelopes are to be returned to the following address:

Health Canada Bid Receiving Unit
Federal Records Centre Building,
161 Goldenrod Driveway, Address Locator 1801B
Ottawa, Ontario K1A 0K9
Attention: Randy Brown

RFSO Reference Number: 1000201293

All bids must be time stamped at the Bid Receiving Unit. Each bid submission envelope must include
-the RFSO reference number and
-the name of the responsible Departmental Representative

Proposals are to be submitted directly to the attention of the Departmental Representative and address shown as the "Issuing Office" on the cover page of this RFSO package.

The onus for submitting bids on time at the specified location rests with the bidder. It is the responsibility of the bidder to ensure correct and timely delivery of the entire bid to the Crown, including all required information and proposal pages.

7.3 Non-Acceptance of Proposals by Facsimile or Electronic Means

Proposals sent by fax, telex, e-mail and telegraphic means will **not** be accepted.

7.4 Closing Date and Time

All proposals must be received at the specified location by 2:00 PM EDT, June 19, 2018. Proposals received after this time will be returned unopened.

7.5 Time Extension to Closing Date

Requests for a time extension to the closing date will not be considered.

7.6 Non-Compliance / Unacceptable Proposals

Failure to meet the mandatory requirements of this RFSO will result in your proposal being declared non-responsive.

Proposals received after the proposal closing time will not be considered and will be returned unopened to the bidder. Further, for any proposals which are found to be non-compliant, the financial part of the bid or proposal will be returned unopened with a letter from Health Canada indicating that the bid/proposal was non-compliant.

7.7 Bidders Conference / Site Visits

N/A

7.8 Announcement of Successful Contractor

The name(s) of the successful bidder(s) will be announced on 'BuyandSell.gc.ca' only upon SOA award and sign-off.

7.9 Rights of the Crown

The Crown reserves the right to:

-reject any or all proposals received in response to this RFSO;
-accept any proposal in whole or in part; and
-cancel and/or re-issue this requirement at any time.

7.10 Standing Offer Agreement (SOA)

The successful Bidder(s) for this requirement will be expected to enter into agreement with Health Canada as per departmental terms and conditions. These terms and conditions will govern and form part of any Call-up issued against this SOA.

7.11 Employment Equity

Please refer to Appendix "A" - Certifications

7.12 Procurement Business Number (PBN)

Public Works and Government Services Canada (PWGSC) has adopted the Procurement Business Number (PBN) for all its purchasing databases, and now requires that its suppliers have one for each of their offices that may be awarded contracts. Register with Contracts Canada's Supplier Registration Information (SRI) service to obtain your PBN. As an existing or potential supplier to the Department, you must obtain a PBN to avoid possible delays of any contract award. It is Health Canada's intention to use this sourcing system for all its procurements of goods and services to which the trade agreements do not apply.

SRI is a database of suppliers who have registered to do business with the Government of Canada. The PBN is created using your Canada Customs and Revenue Agency Business Number to uniquely identify a branch, division or office of your company. Unlike many existing departmental vendor databases, your information in SRI is accessible to all federal government buyers. SRI can help to open up new opportunities with the federal government for requirements not posted on the electronic tendering service, MERX™.

Visit the Contracts Canada Internet site at http://contractscanada.gc.ca/en/busin-e.htm for information and registration procedures. Alternatively, you may contact a Supplier Registration Agent at: 1-800-811-1148 or, in the National Capital Region, at 956-3440.

7.13 Order of Precedence

In the case of any dispute which may arise during the period which may be covered by any ensuing SOA, the following documents will be considered in order of precedence in terms of importance in resolving any disputes between the parties:

The Call-Up Against SOA;
The Health Canada Standing Offer Agreement(s);
Any changes to the terms and conditions contained herein which have been approved by General Counsel for Health Canada;
The Statement of Work in this RFSO;
The terms identified in this RFSO and
The Standing Offer Holder's Proposal.

8.0 Technical Proposal

8.1 General Information

Your technical proposal must meet **all of the Mandatory Requirements** listed in Section 12.0, as well as the **minimum score identified for the Point Rated Requirements** in Section 13.0.

Furthermore, your technical proposal should include the following:

8.2 Proposed Team

8.2.1 Personnel

Identify the proposed personnel, including **Project Manager**, who will be assigned to this contract, describe the role they will be performing, including the amount of direct time dedicated to the project by principals and/or senior personnel, and explain why they are well suited for the work, referring to their qualifications, certifications, education and experience.

If applicable, include a list of proposed sub-contractors, with reference to their capabilities, experience and degree of involvement in the work.

The bidder must certify in the technical proposal that the information provided in all the personnel résumés has been verified to be true and accurate. In addition, for every resource proposed by the bidder who is not an employee of the firm, the actual resource must certify that they are aware that they are being bid as part of the bid/ proposal and state their relationship with the firm.

Please note all **individuals** listed must have or obtain a valid security clearance at the Reliability Level.

8.3 Résumés of Personnel

Attach résumés of proposed personnel.

9.0 Cost / Price Proposal

9.1 General Information

The Price Proposal must contain a detailed breakdown of the **total quoted price**, by phase, or by major tasks, or both. The Price Proposal should address each of the following, if applicable:

9.1.1 Hourly Rate

For each individual and/or labor category to be employed on the project, including subcontractors, indicate the proposed time rate and the estimated time requirement. Although detailed support for the rates is not requested at this time, you should be prepared to substantiate the proposed rates.

9.1.2 Travel

N/A

9.1.3 Goods and Services Tax / Harmonized Sales Tax

Various items in your cost proposal may be subject to GST / HST or custom duties however these are NOT to be included in the cost estimates.

10.0 Enquiries

All enquiries or issues concerning this procurement must be submitted **in writing only** to the Departmental Representative named on the front cover page of this RFSO document **not later than seven (7) working days (June 12, 2018 2: PM, EDT) prior to the bid closing date** to ensure consistency and quality of information to Bidders, the Departmental Representative will provide, simultaneously to all bidders to which this solicitation has been sent,

- any information with respect to significant enquiries received, and
- the replies to such enquiries without revealing their sources,

provided that such enquiries are received no less than seven (7) working days (June 12 2018, 2:00 PM EDT) prior to the bid closing date.

All enquiries and other communications with government officials throughout the solicitation and evaluation period are to be directed **only** to the Departmental Representative named on the front cover page of this RFSO document. **Non-compliance with this condition during the bid solicitation and evaluation period may be sufficient reason for bid disqualification.**

PART III BID SELECTION PROCESS

11.0 Introduction

The Bid Evaluation Committee will evaluate bids, which have been received by the closing date and time stipulated on the front cover of this RFSO and in Section 7.4 (**June 19, 2018, 2:00 PM EDT,**), on the basis of the contents of the Bidder's submitted proposal and NOT on any prior knowledge or experience with the Bidder or the Bidder's work. It is, therefore, the Bidder's responsibility to ensure the proposal is complete, clear and that it provides sufficient detail to allow the evaluators to assess it on the basis of the **Mandatory Requirements** and **Point Rated Requirements** contained herein. Relevant supporting documents should be provided when required as appendices.

The bid evaluation process has three main components, assessment of the:

1) Technical Proposal against **Mandatory Requirements**;
2) Technical Proposal against **Point-Rated Requirements**; and,
3) Cost/Price Proposal.

Each of these is summarized below.

12.0 Mandatory Requirements

12.1 Method of Evaluation

Mandatory requirements are evaluated on a simple pass or fail basis. Failure by bidders to meet any of the mandatory requirements will render the bidder's proposal **non-responsive**. The treatment of mandatory requirements in any procurement process is absolute.

Proposers must meet **all** the mandatory requirements described below. This will be evaluated as either "**Yes**" or "**No**". Proposals not receiving "**Yes**" for any mandatory requirement will ***not*** be considered further.

12.2 Mandatory Criteria

Attention Bidders: Each of the below Mandatory Criteria MUST be included in the technical Proposal. Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria.

Bidders MUST meet ALL the mandatory requirements described below. This will be evaluated as Yes" or "No". Proposals not receiving "Yes" for any mandatory requirement will *not* be considered further.

Mandatory Criteria	Page #	YES	NO
M1. Bidders **MUST** provide demonstrated evidence, by providing a detailed curriculum vitae for each proposed resource, of a minimum total of three(3) years of experience within the last five(5) years (final date of inclusion is March 31st, 2018) of working experience critically assessing toxicological data. This experience could be gained from a consulting firm, pharmaceutical or biotechnology company, regulatory agency or academic institution. The potential consultant should also highlight their area of expertise (e.g. reproductive toxicology, genotoxicity, teratology, general toxicology, etc).			
M2. The resource(s) proposed by the Bidder **MUST** have a minimum of a D.V.M or M.D. or Master's degree from a recognized university, in toxicology or a related discipline. Copy of degree required for each resource. Please note that a 'world equivalency'/credential is required for any non-Canadian degrees.			
M3. All proposed resources **MUST** have individually completed the exercise entitled "'Toxicological evaluation of proposed impurity limits for styrene, Impurity X and Impurity Y in sodium polystyrene sulfonate drug product' as part of this proposal. (See Annex A).			
M4. Certifications at Appendix A Bidders **MUST** sign and submit **ALL** Certifications at Appendix "A" with the technical proposal.			

13.0 Point Rated Requirements

13.1 Method of Evaluation

A proposal with a score less than 70% per question for technical compliance will be considered **non responsive**, and eliminated from the competition.

13.2 Point Rated Requirements

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria.			
Rated Criteria		**Points allocated for the criteria**	**Score**
R1. Experience The bidders proposed resource(s) must have demonstrated experience working in the private pharmaceutical industry, or regulatory body in toxicology relative to the duties (see Work Breakdown Structure - Section 2.0) **Demonstrated Experience**: **<u>Rating Scale:</u>** - =/> 10 years experience - 10 points - 5 to 9 years experience - 8 points - 3 to 4 years experience - 4 points		10	
R2. Education Additional points will be allocated for certifications such as: -diplomat of American Board of Toxicology -European Registered Toxicologist (5 points each up to a maximum of 10 points)		10	

R3. Sample of Work - each proposed resource is to provide a sample of work (up to a maximum of 100 single sided pages including all texts, tables, appendices in a legible font, not including any references) to support their knowledge and experience in critically assessing toxicological data and performing risk-benefit evaluations for human therapeutic products. (See rating table below)		50	
R4. Exercise - Taking into account Health Canada and the International Conference on Harmonization guidelines (www.ICH.org) and other relevant guidelines, each proposed resource **MUST** complete the Exercise entitled: 'Toxicological evaluation of proposed impurity limits for styrene, Impurity X and Impurity Y in sodium polystyrene sulfonate drug product' attached as Annex A. (See rating table below). Up to 15 pages only, 8.5. x 11 paper, single sided, 11 pt font.		30	
TOTAL **Minimum Points Required**		**100** **70**	

R3 - Scoring of Work Samples

Criteria	**Guidance for scoring**	**Points/50**
Quality of the presentation	-Organization -Logical flow of information	5
Quality of written language	read and understand -Grammar and spelling	5
Quality of the science	-Are quality references provided? -Knowledge of toxicology -Quality discussion of toxicological findings -Knowledge of relevant international guidelines	25
Quality of summaries, conclusions and recommendations	-Are main issues well presented? -Are issues addressed appropriately? -Ability to extrapolate animal data to the human situation -Ability to perform risk-benefit evaluations	15

R4 - Scoring for Exercise - Annex 1

Criteria	Guidance for scoring	Points/30
Quality of the presentation	-Organization -Logical flow of information	5
Quality of written language	-Easy to read and understand -Grammar and spelling	5
Quality of the science	-Are relevant references provided? -Knowledge of toxicology -Quality discussion of toxicological findings -Knowledge of relevant regulatory guidelines	15
Quality of summaries, conclusions and recommendations	-Are main issues well presented? -Are issues addressed appropriately? -Ability to extrapolate animal data to the human situation -Ability to perform risk-benefit evaluations	5

14.0 BASIS OF AWARDING CONTRACT

Compliant Combined Rating of Technical Merit and Price:

It is understood by the parties submitting proposals that, to qualify, bidders must meet all mandatory requirements as well as the minimum score identified for the point-rated criteria. The contract will be awarded based on a determination of best value taking into account both the technical merit of the proposals and the price evaluations. To arrive at an overall score achieved by a firm, a weighting has been established whereby technical merit will be valued at 80% of the bid and price at 20%.

Example 1 - Contractor Ranking

For the purpose of ranking all technically acceptable proposals, the following ratio will factor the technical and the price component to establish a total percentage score:

Technical : 80% Price: 20%

Technical Score = $\frac{\text{Bidder's Points}}{\text{Maximum Points}} \times 80\%$ Cost Score = $\frac{\text{Lowest Bid}}{\text{Bidder's Cost}} \times 20\%$

Total Score = Technical Score + Cost Score

15.0 Debriefing

A debriefing will be provided, on request, only following entry by Health Canada into a Standing Offer arrangement with the successful Bidder(s). Should a Bidder desire a debriefing, the Bidder should contact the Contracting Officer identified in section 7.2 of the RFSO. The debriefing will include an outline of the reasons the submission was not successful, by referencing the evaluation criteria. The confidentiality of information relating to other submissions will be protected.

PART IV INFORMATION TO ALL BIDDER'S FOR PROPOSAL SUBMISSION
Refer to Section 7.0 Instructions to Bidders for Proposal Completion of the RFSO

Below is a CHECKLIST for ALL Bidders to complete.
Bidders can include this checklist in their proposal.

16.0 RFSO BIDDER'S CHECKLIST

PLEASE USE THIS LIST TO ENSURE BIDDERS HAVE PROVIDED HEALTH CANADA WITH ALL OF THE REQUESTED INFORMATION.
FAILURE TO PROVIDE ALL OF THE DOCUMENTS LISTED BELOW WILL RESULT IN YOUR BID BEING ELIMINATED.

The following TWO (2) separate packages will be required:

PACKAGE 1 - TECHNICAL PROPOSAL: Refer to Part 12.2 and 12.3
Please provide "five (5) copies" of the following:

□Cover letter (1 original and 4 copies) signed by the individual or an authorized representative of the firm;
□Technical proposal details comprising of information as indicated in Section 8 of the RFSO and to include
□Completed table 12.2 indicating page numbers for all Mandatory Criteria listed
□Completed table 13.2 indicating page numbers for all Rated Criteria listed
□Copies of resumes for all individuals proposed outlining experience as per Section 8 and M1;
□Copy of university degree as per Mandatory Criteria M2 for all individuals involved and copy of equivalency if indicated.
□Signed Certifications found in Appendix A as per Mandatory Criteria M5
□Attached sample of work (maximum of 100 pages) as per Rated Criteria R3 duly organized and paginated.
□Completed exercise "Toxicological evaluation of proposed impurity limits for styrene, Impurity X and Impurity Y in sodium polystyrene sulfonate drug product" (found in Annex A) as per Mandatory Criteria R4.

Please Note:

Read information regarding Security Clearance requirements as per clause 3.7

NOTE: Bidders MUST have the required Security Clearance for ALL resources at the Reliability security level before a Call-up can be issued. If the Bidder's resource(s) have the necessary security clearance, please provide the PWGSC CISD Security Number within their resume. This number will be verified with PWGSC.

PACKAGE 2 - COST PROPOSAL

In a Separate Sealed Envelope, please include TWO (2) copies of your Cost Proposal as outlined in Section 9 of the RFSO.

PLEASE NOTE THE RFSO REFERENCE NUMBER, AND THE NAME OF THE CONTRACT OFFICER WHICH MUST BE MARKED ON ALL DOCUMENTS, BINDERS AND RESPECTIVE ENVELOPES.

Appendix "A"

BIDDER's INFORMATION AND CERTIFICATIONS
(MUST BE COMPLETED AND SUBMITTED WITH THE TECHNICAL PROPOSAL)

The following information/certifications are required with the bid.
Failure to provide a copy of the information/certifications appendix document with each copy of the technical proposal will render your bid non responsive.

1.0 Legal name and bidder's information (print clearly)

Bidder's Legal Name _____

Bidder's Complete Address _____

_____

Bidder's Phone number (_____)_____

Bidder's Authorized Representative _____

Bidder's Authorized Representative Phone number (_____) _____

Bidder's Authorized Representative e-mail _____

Bidder's Procurement Business Number _____

Bidder's province in which he is incorporated. _____

2.0 Compliancy with Terms and Conditions

The Bidder by signing below hereby certifies that it has read the RFP in its entirety, including the Statement of Work, and signifies compliance with and acceptance of all the articles, clauses, terms and conditions contained or referenced in this RFSO document.

_____ _____
Signature of the Authorized Representative **Date**

3.0 Certification of Education, Experience and Qualifications

Offers, to be considered responsive, must contain the following certification:

"The Bidder hereby certifies that all statements made with respect to education and experience are true and that any person proposed by the Bidder to perform the work or part of the work is either an employee of the Bidder or under a written agreement to provide services to the Bidder."

The Crown reserves the right to verify the above certification and to declare the bid non-responsive for any of the following reasons:

- **unverifiable or untrue statement;**
- **unavailability of any person proposed on whose statement of education and experience the Crown relied to evaluate the offer and award the Contract.**

Signature of the Authorized Representative

_____

Date _____

4.0 Certification of Availability and Status of Personnel

Availability of Personnel and Facility

The Bidder certifies that, should it be authorized to provide services under any Contract resulting from this solicitation, the persons and facility proposed in its offer will be available to commence performance of the work within a reasonable time from Contract award, and will remain available to perform the work in relation to the fulfillment of this requirement.

Status of Personnel

If the Bidder has proposed any person in fulfillment of this requirement who is not an employee of the Bidder, the Bidder hereby certifies that it has written permission from such person (or the employer of such person) to propose the services of such person in relation to the work to be performed in fulfillment of this requirement and to submit such person's résumé to the Contracting Authority.

During the offer evaluation, the Bidder MUST upon the request of the Contracting Authority provide a copy of such written permission, in relation to any or all employees proposed. The Bidder agrees that failure to comply with such a request may lead to disqualification of the Bidder's offer from further consideration.

_____ _____

Signature of the Authorized Representative **Date**

5.0 Bid Validity Period:

This is to certify below that all pricing identified in the bid/proposal will be valid for a period of one hundred and twenty (120) days from the closing date of the RFSO.

Signature of Authorized Representative of the Bidder **Date**

6.0 Employment Equity (over 200K)

The Federal Contractors Program for Employment Equity requires that some organizations bidding for federal government contracts make a formal commitment to implement employment equity, as a pre-condition to the validation of their bids. All bidders must check the applicable box(es) below. Failure to do so may render the bid non responsive.

Program requirements do not apply for the following reason(s):

( ) bid is less than $200,000;
( ) this organization has fewer than 100 permanent part time and/or full time employees across Canada;
( ) this organization is a federally regulated employer;

or, program requirements do apply:

( ) copy of signed Certificate of Commitment is enclosed; or
( ) Certificate number is _____

NOTE: The Federal Contractors Program for Employment Equity applies to Canadian based bidders only. The Certificate of Commitment criteria and other information about the Federal Contractors Program for Employment Equity are available in the PWGSC Standard Acquisition Clauses and Conditions (SACC) Manual, Section 2, and on the Government Electronic Tendering Service.

_____ _____
Signature of Authorized Representative of the bidder Date

7.0 Joint Venture/Partnership

A joint venture is not considered a "person" for registration purposes, whereas a partnership is. Therefore, a partnership can have a BN: a joint venture cannot. A joint venture is limited in scope; a partnership is generally an ongoing business relationship that exists between persons carrying on common business.

A joint venture is an arrangement where two or more person (participants) work together in a limited and defined business undertaking. Ordinarily, all participants of the joint venture contribute assets, share risks, and have mutual liability.

The bidder certified that his bid is submitted to the Crown as a: (please choose one)

Sole proprietary business [ ]

A Joint Venture (bidder must provide detail) [ ]

Partnership (bidder must provide detail) [ ]

Signature of Authorized Representative of the bidder **Date**

Appendix 'B'

SECURITY REQUIREMENT CHECKLIST

Government of Canada / Gouvernement du Canada

Contract Number / Numéro du contrat
1000201293
Security Classification / Classification de sécurité Unclassified

SECURITY REQUIREMENTS CHECK LIST (SRCL)
LISTE DE VÉRIFICATION DES EXIGENCES RELATIVES À LA SÉCURITÉ (LVERS)

PART A - CONTRACT INFORMATION / PARTIE A - INFORMATION CONTRACTUELLE

1. Originating Government Department or Organization / Ministère ou organisme gouvernemental d'origine: Health Canada	2. Branch or Directorate / Direction générale ou Direction: HPFB/TPD
3. a) Subcontract Number / Numéro du contrat de sous-traitance	3. b) Name and Address of Subcontractor / Nom et adresse du sous-traitant

4. Brief Description of Work / Brève description du travail
Required medical expertise to assist in various drug reviews

5. a) Will the supplier require access to Controlled Goods? Le fournisseur aura-t-il accès à des marchandises contrôlées?	☑ No Non	☐ Yes Oui
5. b) Will the supplier require access to unclassified military technical data subject to the provisions of the Technical Data Control Regulations? Le fournisseur aura-t-il accès à des données techniques militaires non classifiées qui sont assujetties aux dispositions du Règlement sur le contrôle des données techniques?	☑ No Non	☐ Yes Oui
6. Indicate the type of access required / Indiquer le type d'accès requis		
6. a) Will the supplier and its employees require access to PROTECTED and/or CLASSIFIED information or assets? Le fournisseur ainsi que les employés auront-ils accès à des renseignements ou à des biens PROTÉGÉS et/ou CLASSIFIÉS? (Specify the level of access using the chart in Question 7. c) (Préciser le niveau d'accès en utilisant le tableau qui se trouve à la question 7. c)	☐ No Non	☑ Yes Oui
6. b) Will the supplier and its employees (e.g. cleaners, maintenance personnel) require access to restricted access areas? No access to PROTECTED and/or CLASSIFIED information or assets is permitted. Le fournisseur et ses employés (p. ex. nettoyeurs, personnel d'entretien) auront-ils accès à des zones d'accès restreintes? L'accès à des renseignements ou à des biens PROTÉGÉS et/ou CLASSIFIÉS n'est pas autorisé.	☑ No Non	☐ Yes Oui
6. c) Is this a commercial courier or delivery requirement with no overnight storage? S'agit-il d'un contrat de messagerie ou de livraison commerciale sans entreposage de nuit?	☑ No Non	☐ Yes Oui

7. a) Indicate the type of information that the supplier will be required to access / Indiquer le type d'information auquel le fournisseur devra avoir accès

Canada ☑	NATO / OTAN ☐	Foreign / Étranger ☐

7. b) Release restrictions / Restrictions relatives à la diffusion

No release restrictions Aucune restriction relative à la diffusion ☑	All NATO countries Tous les pays de l'OTAN ☐	No release restrictions Aucune restriction relative à la diffusion ☐
Not releasable À ne pas diffuser ☐		
Restricted to: / Limité à : ☐	Restricted to: / Limité à : ☐	Restricted to: / Limité à : ☐
Specify country(ies): / Préciser le(s) pays :	Specify country(ies): / Préciser le(s) pays :	Specify country(ies): / Préciser le(s) pays :

7. c) Level of information / Niveau d'information

PROTECTED A / PROTÉGÉ A ☑	NATO UNCLASSIFIED / NATO NON CLASSIFIÉ ☐	PROTECTED A / PROTÉGÉ A ☐
PROTECTED B / PROTÉGÉ B ☑	NATO RESTRICTED / NATO DIFFUSION RESTREINTE ☐	PROTECTED B / PROTÉGÉ B ☐
PROTECTED C / PROTÉGÉ C ☐	NATO CONFIDENTIAL / NATO CONFIDENTIEL ☐	PROTECTED C / PROTÉGÉ C ☐
CONFIDENTIAL / CONFIDENTIEL ☐	NATO SECRET / NATO SECRET ☐	CONFIDENTIAL / CONFIDENTIEL ☐
SECRET / SECRET ☐	COSMIC TOP SECRET / COSMIC TRÈS SECRET ☐	SECRET / SECRET ☐
TOP SECRET / TRÈS SECRET ☐		TOP SECRET / TRÈS SECRET ☐
TOP SECRET (SIGINT) / TRÈS SECRET (SIGINT) ☐		TOP SECRET (SIGINT) / TRÈS SECRET (SIGINT) ☐

Government of Canada / Gouvernement du Canada

Contract Number / Numéro du contrat
1000201293
Security Classification / Classification de sécurité
Unclassified

PART A (continued) / PARTIE A (suite)

8. Will the supplier require access to PROTECTED and/or CLASSIFIED COMSEC information or assets? — ☑ No / Non ☐ Yes / Oui
Le fournisseur aura-t-il accès à des renseignements ou à des biens COMSEC désignés PROTÉGÉS et/ou CLASSIFIÉS?
If Yes, indicate the level of sensitivity:
Dans l'affirmative, indiquer le niveau de sensibilité :

9. Will the supplier require access to extremely sensitive INFOSEC information or assets? — ☑ No / Non ☐ Yes / Oui
Le fournisseur aura-t-il accès à des renseignements ou à des biens INFOSEC de nature extrêmement délicate?

Short Title(s) of material / Titre(s) abrégé(s) du matériel :
Document Number / Numéro du document :

PART B - PERSONNEL (SUPPLIER) / PARTIE B - PERSONNEL (FOURNISSEUR)

10. a) Personnel security screening level required / Niveau de contrôle de la sécurité du personnel requis

☑ RELIABILITY STATUS / COTE DE FIABILITÉ	☐ CONFIDENTIAL / CONFIDENTIEL	☐ SECRET / SECRET	☐ TOP SECRET / TRÈS SECRET
☐ TOP SECRET– SIGINT / TRÈS SECRET – SIGINT	☐ NATO CONFIDENTIAL / NATO CONFIDENTIEL	☐ NATO SECRET / NATO SECRET	☐ COSMIC TOP SECRET / COSMIC TRÈS SECRET
☐ SITE ACCESS / ACCÈS AUX EMPLACEMENTS			

Special comments:
Commentaires spéciaux : _____

NOTE: If multiple levels of screening are identified, a Security Classification Guide must be provided.
REMARQUE : Si plusieurs niveaux de contrôle de sécurité sont requis, un guide de classification de la sécurité doit être fourni.

10. b) May unscreened personnel be used for portions of the work? — ☑ No / Non ☐ Yes / Oui
Du personnel sans autorisation sécuritaire peut-il se voir confier des parties du travail?
If Yes, will unscreened personnel be escorted? — ☐ No / Non ☐ Yes / Oui
Dans l'affirmative, le personnel en question sera-t-il escorté?

PART C - SAFEGUARDS (SUPPLIER) / PARTIE C - MESURES DE PROTECTION (FOURNISSEUR)

INFORMATION / ASSETS / RENSEIGNEMENTS / BIENS

11. a) Will the supplier be required to receive and store PROTECTED and/or CLASSIFIED information or assets on its site or premises? — ☑ No / Non ☐ Yes / Oui
Le fournisseur sera-t-il tenu de recevoir et d'entreposer sur place des renseignements ou des biens PROTÉGÉS et/ou CLASSIFIÉS?

11. b) Will the supplier be required to safeguard COMSEC information or assets? — ☑ No / Non ☐ Yes / Oui
Le fournisseur sera-t-il tenu de protéger des renseignements ou des biens COMSEC?

PRODUCTION

11. c) Will the production (manufacture, and/or repair and/or modification) of PROTECTED and/or CLASSIFIED material or equipment occur at the supplier's site or premises? — ☑ No / Non ☐ Yes / Oui
Les installations du fournisseur serviront-elles à la production (fabrication et/ou réparation et/ou modification) de matériel PROTÉGÉ et/ou CLASSIFIÉ?

INFORMATION TECHNOLOGY (IT) MEDIA / SUPPORT RELATIF À LA TECHNOLOGIE DE L'INFORMATION (TI)

11. d) Will the supplier be required to use its IT systems to electronically process, produce or store PROTECTED and/or CLASSIFIED information or data? — ☑ No / Non ☐ Yes / Oui
Le fournisseur sera-t-il tenu d'utiliser ses propres systèmes informatiques pour traiter, produire ou stocker électroniquement des renseignements ou des données PROTÉGÉS et/ou CLASSIFIÉS?

11. e) Will there be an electronic link between the supplier's IT systems and the government department or agency? — ☑ No / Non ☐ Yes / Oui
Disposera-t-on d'un lien électronique entre le système informatique du fournisseur et celui du ministère ou de l'agence gouvernementale?

Government of Canada / Gouvernement du Canada

Contract Number / Numéro du contrat
1000201293
Security Classification / Classification de sécurité
Unclassified

PART C - *(continued)* / PARTIE C - *(suite)*

For users completing the form manually use the summary chart below to indicate the category(ies) and level(s) of safeguarding required at the supplier's site(s) or premises.
Les utilisateurs qui remplissent le formulaire manuellement doivent utiliser le tableau récapitulatif ci-dessous pour indiquer, pour chaque catégorie, les niveaux de sauvegarde requis aux installations du fournisseur.

For users completing the form online (via the Internet), the summary chart is automatically populated by your responses to previous questions.
Dans le cas des utilisateurs qui remplissent le formulaire en ligne (par Internet), les réponses aux questions précédentes sont automatiquement saisies dans le tableau récapitulatif.

SUMMARY CHART / TABLEAU RÉCAPITULATIF

Category / Catégorie	PROTECTED / PROTÉGÉ			CLASSIFIED / CLASSIFIÉ			NATO				COMSEC					
	A	B	C	CONFIDENTIAL / CONFIDENTIEL	SECRET	TOP SECRET / TRÈS SECRET	NATO RESTRICTED / NATO DIFFUSION RESTREINTE	NATO CONFIDENTIAL / NATO CONFIDENTIEL	NATO SECRET	COSMIC TOP SECRET / COSMIC TRÈS SECRET	PROTECTED / PROTÉGÉ A	PROTECTED / PROTÉGÉ B	PROTECTED / PROTÉGÉ C	CONFIDENTIAL / CONFIDENTIEL	SECRET	TOP SECRET / TRÈS SECRET
Information / Assets / Renseignements / Biens																
Production																
IT Media / Support TI																
IT Link / Lien électronique																

12. a) Is the description of the work contained within this SRCL PROTECTED and/or CLASSIFIED?
La description du travail visé par la présente LVERS est-elle de nature PROTÉGÉE et/ou CLASSIFIÉE?

☑ No / Non ☐ Yes / Oui

If Yes, classify this form by annotating the top and bottom in the area entitled "Security Classification".
Dans l'affirmative, classifier le présent formulaire en indiquant le niveau de sécurité dans la case intitulée « Classification de sécurité » au haut et au bas du formulaire.

12. b) Will the documentation attached to this SRCL be PROTECTED and/or CLASSIFIED?
La documentation associée à la présente LVERS sera-t-elle PROTÉGÉE et/ou CLASSIFIÉE?

☑ No / Non ☐ Yes / Oui

If Yes, classify this form by annotating the top and bottom in the area entitled "Security Classification" and indicate with attachments (e.g. SECRET with Attachments).
Dans l'affirmative, classifier le présent formulaire en indiquant le niveau de sécurité dans la case intitulée « Classification de sécurité » au haut et au bas du formulaire et indiquer qu'il y a des pièces jointes (p. ex. SECRET avec des pièces jointes).

Government of Canada / Gouvernement du Canada

Contract Number / Numéro du contrat
1000201293
Security Classification / Classification de sécurité Unclassified

PART D - AUTHORIZATION / PARTIE D - AUTORISATION

13. Organization Project Authority / Chargé de projet de l'organisme

Name (print) - Nom (en lettres moulées)	Title - Titre	Signature
Mandy Collier	Director, OPPRS, TPD	Mcollier

Telephone No. - N° de téléphone	Facsimile No. - N° de télécopieur	E-mail address - Adresse courriel	Date
613-946-1246		mandy.collier@canada.ca	Apr. 30/18.

14. Organization Security Authority / Responsable de la sécurité de l'organisme

Name (print) - Nom (en lettres moulées)	Title - Titre	Signature
DAVID L WILSON	SECURITY OFFICER	

Telephone No. - N° de téléphone	Facsimile No. - N° de télécopieur	E-mail address - Adresse courriel	Date
204 288 0334	204 594 8160	DAVID.L.WILSON@CANADA.CA	8/5/18

15. Are there additional instructions (e.g. Security Guide, Security Classification Guide) attached?
Des instructions supplémentaires (p. ex. Guide de sécurité, Guide de classification de la sécurité) sont-elles jointes?

☑ No / Non ☐ Yes / Oui

16. Procurement Officer / Agent d'approvisionnement

Name (print) - Nom (en lettres moulées)	Title - Titre	Signature
RANDY BROWN	SENIOR PROCUREMENT OFFICER	

Telephone No. - N° de téléphone	Facsimile No. - N° de télécopieur	E-mail address - Adresse courriel	Date
613-941-2014		randy.brown2@canada.ca	2018/05/08

17. Contracting Security Authority / Autorité contractante en matière de sécurité

Name (print) - Nom (en lettres moulées)	Title - Titre	Signature
DAVID L WILSON	SECURITY OFFICER	

Telephone No. - N° de téléphone	Facsimile No. - N° de télécopieur	E-mail address - Adresse courriel	Date
204 288 0334	204 594 8160	DAVID.L.WILSON@CANADA.CA	8/5/18

Appendix "C"

FOR INFORMATION PURPOSES ONLY PROTECTED "B" WHEN COMPLETED

CONFLICT OF INTEREST INFORMATION SHEET

Please Note: This Conflict of Interest Sheet is for informational gathering purposes only. The collection of this data in no way infers that Health Canada is offering you a contract.
No obligation or commitment is being offered.

Date:

_____

Name of Manager:

Bureau:

_____

Telephone No.:

_____

Proposed Resource:

_____

ORAL TELEPHONE DISCUSSION

Please answer Yes or No for each of the following questions and provide additional details as needed. Use a separate sheet of paper if required. Answering Yes to any of the questions does not necessarily mean that a potential resource is disqualified from consideration for an assignment but requires that the details surrounding the positive response will require further discussion.

	YES	NO	COMMENTS
1. Have you ever been employed by _____, a parent company, a subsidiary or a competitor as an employee? **If Yes, please answer the following questions:** **§ When did you terminate employment?** **§ What was the nature of position?**			
2. Have you received any consulting opportunities, contracts and/or grants from _____, a parent company, a subsidiary or a competitor? (This may include contracts and grants imputed through your employer) **If Yes, please answer the following questions:** **§ What was the value of the contract/grant or consulting opportunity?** **§ What was the nature of the work that was performed?**			
3. Have you participated as the principal investigator in scientific studies related to_____?			
4. Have you participated on committees advising _____ in regard to _____?			

5. Have you performed any research work funded by grants from _____ company? **related to the drug in question? When was the work performed? related to any other drug? What was the drug? When was the work performed?** **. If YES, when was the grant/funded ceased?**			
6. Do you own shares of the sponsor, a parent company, a subsidiary or a competitor? **If yes, what is their current value?**			
7. Do your spouse and/or children, have any financial interest _____, a parent company, a subsidiary or a competitor?			
8. Are your spouse or children employed by _____, a parent company, a subsidiary or a competitor? **If Yes, please specify, the following** **§ What is the nature of the work performed?**			
(9) Have you ever worked as a public servant for the federal government? If so please advise date of termination.			

OTHER CONFLICT OF INTEREST QUESTIONS

Please answer yes or no for each of the following questions and provide additional details as needed. Use a separate sheet of paper if required. If you answer "Yes" to any of the questions, please contact the Health Canada Manager named above to discuss further details. If you have answered "No" to all the questions, please sign and return to the Health Canada Manager.

	YES	NO	COMMENTS
(10) Have you completed any research related to drugs/medical devices to treat _____?* Please provide details of research.			

(11) Do you have any previous, present and/or potential contracts, grants and/or contributions with the pharmaceutical and/or medical device industry related to drugs to treat _____? **If yes, please answer the following:** **When was the work performed?** **What was the nature of the work?**			
(12) Have you provided any advice to or have close association with pharmaceutical and/or medical device industry related to _____ type of drugs/medical devices? **If yes, What was the nature of the advice?**			
(13) Have you produced any publications that were sponsored/supported/funded by the pharmaceutical and/or medical device industry related to _____ type of drugs/medical devices? **If yes, please name and date the publications, and the amount of support provided.**			
(14) To the best of your knowledge do any of the following persons or institutions have a financial interest in _____? **An organization in which you serve as an officer, director, trustee, partner or employee.** **A person or organization with which you are negotiating for prospective employment or have an arrangement for prospective employment.**			
(15) Have you ever participated (ie. delivered speeches) in seminars or promotional meetings that dealt with_____? **If yes, please provide the date and name of the meeting/seminar.**			
(16) Have you authored or co-authored or do you have in preparation any scientific paper or other document concerning _____? **If yes, please provide a copy of the manuscript or journal citation.**			

(17) Have you attended conferences and meetings where all or part of the travel and accommodation costs were provided by _____, a parent company, a subsidiary or a competitor? **If yes, please give the dates and details.**			
(18) Have you received any gifts and hospitality of significant value (over $1000) from _____ a parent company, a subsidiary or a competitor? **If yes, please give the dates and details?**			
(19) Have you participated as an Expert Witness for _____, a parent company, a subsidiary or a competitor? **If yes, please provide the details?**			
(20) Do you hold any Patents/Royalties or Trademarks with _____ related to _____?			
(21) Are you financially affiliated with a manufacturer, supplier or vendor of articles regulated under the Food and Drugs Act and Regulations? **If yes, in what manner?**			
(22) Are you engaged in the design, manufacture, promotion or sale of articles regulated under the Act or the authorized representative of any of those parties? **If yes, in what manner?**			
(23) Does your spouse and/or minor children, have any financial interest in any manufacturer, supplier, or vendor of articles regulated under the Act. **If yes, please specify the amount and manner of the interest.**			
(24) Are you involved in decisions to fund grants, cooperative agreements or contracts? **If YES: With what organizations _____?** **What has been the nature of your involvement?**			
(25) Do you engage in any lobbying activities? Do you have any memberships in special interest groups? **If yes, please specify.**			

(26) Any other information which was not covered by the questions that can be construed as a real, potential or perceived conflict of interest? (use additional sheet if necessary)			

"I declare that the information I have provided above is true and accurate to the best of my knowledge."

_____ _____

Signature **Date**

FOR HEALTH CANADA USE ONLY:

I have verified the information contained in this sheet and have found the following:

☐ No conflict of interest

☐ Minor conflict of interest

☐ Conflict of Interest

_____ _____

Divisional Manager Signature Date

_____ _____

Bureau Director Signature Date

ANNEX A - Exercise

Fictive case exercise

Toxicological evaluation of proposed limits for styrene, Impurity X and Impurity Y in sodium polystyrene sulfonate drug product

A Pharmaceutical Sponsor has submitted an Abbreviated New Drug Submission (ANDS) for a potassium-exchange resin that is orally administered at a maximum dose of 75 g per day. As the resin passes through the gastrointestinal tract, the resin removes potassium ions by exchanging them for sodium ions. The resin is not absorbed from the gastrointestinal tract.

The Sponsor has proposed a limit of 2 ppm for styrene, 2 ppm for Impurity X and 2 ppm for Impurity Y in the drug product. The Sponsor submitted (Q)SAR reports for Impurity X and Impurity Y. As assessed by DEREK and Sarah, Impurity X is predicted to be negative for mutagenicity and Impurity Y is predicted to be positive for mutagenicity. No other data was submitted for Impurity X or Impurity Y. Per ICH Q3B(R2), the qualification threshold for impurities in a drug product is 0.15% (Table 1). Potentially mutagenic impurities are regulated per ICH M7.

Table 1: Reporting, identification and qualification thresholds per ICH Q3B(R2)

Maximum daily dose	Reporting threshold	Identification Threshold	Qualification Threshold
> 1g or 2 g	0.05%	0.10%	0.15%

In order to proceed with the review of this drug submission, it is necessary to determine if each of the Sponsor's proposed impurity limits are qualified. You are requested to write a memo no longer than 10 pages detailing the rationale for your recommendation. You may wish to consider the following when writing your recommendation:

1. Toxicity of styrene, Impurity X and Impurity Y.
2. Human exposure to each impurity.
3. Relevant regulatory guidelines including ICH Q3B(R2) and ICH M7(R1).
4. The conditions of use for sodium polystyrene sulfonate.
5. Risk-benefit assessment.