



Health  
Canada

Santé  
Canada

*Your health and  
safety... our priority.*

*Votre santé et votre  
sécurité... notre priorité.*

## Request form for individuals

### Request for Disclosure of CBI under s21.1(3)(c) of the *Food and Drugs Act*

<b>1. Personal and Professional Information</b>	
<b>Name</b> (Principal applicant)	<b>Professional Title &amp; Employer</b>
<b>Professional Qualifications</b> (including relevant institutions and dates)	
<b>Street Address</b>	
<b>City</b>	<b>Prov./Territory</b>
<b>Postal Code</b>	<b>Country</b>
<b>Primary Phone Number</b>	<b>Alternative Phone Number</b>
<b>Email</b>	

## Information requested

Have you consulted all available sources of information prior to submitting this request?

Yes      No - *Please summarize your efforts to obtain this information, including other sources approached and results of your efforts, where relevant.*

Name of the health product(s) to which the information relates:

Regulatory functions to which the information relates:

clinical trials

market authorization

post-market surveillance

compliance and enforcement

other

Please briefly describe the information that you are seeking from Health Canada:

## 2. Project summary

Please attach a summary of the project for which you are seeking the information (maximum 1,000 words). Include headings that respond to the following questions:

- What are the perceived health and/or safety issues associated with the therapeutic product?
- What is the proposed objective of your project?
- How do you propose to carry out your project?
- How will the proposed project accomplish the stated objective?
- How will the project results be disseminated?

In addition to the summary, you may attach publications or other documents related to your project.

Project summary attached

Does your project have a commercial purpose?

Yes

No

Supporting publications, other documents attached (please list below)

**Preferred language for receiving future communications:**

French      or      English

**Certification:** *I certify that the information included in this request is accurate and complete.*

\_\_\_\_\_  
Signature

## PRIVACY NOTICE

The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to process requests for confidential business information (CBI) authorized under paragraph 21.1(3)(c) of the *Food and Drugs Act*.

**Purpose of collection:** Your personal information is used to determine whether requested CBI may be disclosed to you. This information will be reviewed by a committee of senior Health Canada officials who will assess whether you qualify under the Act as “a person who carries out functions relating to the protection or promotion of human health or the safety of the public.”

**Other uses or disclosures:** Health Canada may notify the public and/or the originator of the requested information of your request for CBI. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

**Refusal to provide the information:** Failure to provide the requested information will prevent the assessment of your qualifications under paragraph 21.1(3)(c) and will consequently prevent the processing of your request.

**For more information:** This personal information collection will be described in Info Source, available online at [infosource.gc.ca](http://infosource.gc.ca). Refer to the personal information bank (to come).

**Your rights under the *Privacy Act*:** In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-954-9165 or [privacy-vie.privee@hc-sc.gc.ca](mailto:privacy-vie.privee@hc-sc.gc.ca). You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date : mm/dd/yyyy

## Instructions

Health Canada has discretionary authority under the *Food and Drugs Act* to disclose CBI to individuals and corporations. This form is for individual requests. A form for requests on behalf of a corporation is available on request.

1. **Personal and Professional Information:** Provide all information relevant to your request. To be eligible, the applicant must carry out functions relating to the protection or promotion of human health or the safety of the public.
2. **Information Requested:** Describe the information that you are requesting as specifically as you can, including the product(s) (common and/or brand names) and the regulatory function(s) to which the information relates. Please first consult the resources listed under *Tools* page of the guidance document to help identify the information required. Health Canada's authority under paragraph 21.1(3)(c) of the *Food and Drugs Act* to disclose CBI applies to regulatory information related to therapeutic products, including prescription and non-prescription drugs, vaccines, blood and blood products, donor semen for assisted conception, gene and cell therapies, tissues and organs, and medical devices. It does not apply to natural health products.
3. **Project summary:** describe the research project or other activity for which you are seeking access to CBI, including how the purpose for obtaining access to the CBI is related to the protection or promotion of human health or the safety of the public.

Health Canada's authority under the *Food and Drugs Act* to disclose CBI to individuals or corporations can be used only for a purpose related to the protection or promotion of human health or the safety of the public. Health Canada will not disclose CBI for commercial uses.