

Standard Operating Procedure		SOP Number: CC-017-01	
Title: Product Complaints		Effective:	
Prepared by: _____ Date: _____		Approved by: _____ Date: _____	

1. Purpose/Scope

To establish a procedure for processing all product quality complaints and adverse reactions received.

2. Responsibilities

Quality Assurance Person (QAP)
 Responsible Person in Charge (RPIC)
 Alternate Responsible Person in Charge (A/RPIC)
 Customer Service Representative (CSR)
 Quality Assurance Representative

3. Associated Documents

CC-017-F01 Product Complaint Form
 CC-017-F02 Product Return Letter
 CC-017-F03 Product Return Form

4. Definitions Not

Applicable

5. References

Access to Cannabis for Medical Purposes Regulations. SOR/2016-230. February 13, 2017

6. Procedure – Receiving Product Complaints

- 6.1. Processes are in place through quality agreements requiring all product quality complaints to be forwarded to the applicable supplier for investigation and where applicable notification to Health Canada for adverse reactions. Assessment of adverse reactions are at the discretion of the supplier.
- 6.2. Product complaints are received by Customer Service Representative, through verbal, written or electronic communication.
- 6.3. All product complaints must be documented on the Product Complaint Form (CC-017-F01).
- 6.4. Non product quality complaints such as service and delivery do not need to be documented on the Product Complaint Form (CC-017-F01).

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7. Procedure – Product Quality Complaints

7.1. Complaints which impact direct product quality or adverse reactions are sent to QA. These include but are not limited to:

- ☐ Adverse effects/sickness (noxious and unintended response)
- ☐ Foreign Material found – glass, plastic, metal, etc.
- ☐ Product is moldy, excessively wet, excessively dry
- ☐ Bottle weights are significantly different than described
- ☐ Other complaints that may impact more than one patient or bottle that would have a high risk to a patient.

7.2. The individual receiving a product quality complaint or adverse event must complete Section A of the Product Complaint Form (CC-017-F01) verbatim.

7.3. The Product Complaint Form is forwarded to a Quality Assurance Representative.

7.4. The Quality Assurance Representative logs the complaint and assigns a unique reference number to each complaint which is recorded on the Product Complaint Form.

7.5. The complaint is forwarded to the supplier for investigation.

7.6. A copy of the Product Complaint Report in a binder as well as in the electronic filing system.

8. Procedure - Complaint Product Sample

8.1. If a complaint sample is available for investigation, a Return Package including a Product Return Form (CC-017-F03), prepaid Canada Post Return Label and a tamper evident seal packaging is sent to the client.

9. Procedure - Complaints about Service or Other Non-Product Quality Attributes

9.1. Complaints about service or any other non-product quality complaints do not need to be investigated by quality or provided to the supplier for investigation.

10. Revision History

Version	Reason for Revision	Date
01	New	

Title: Product Complaint Form	Doc. Type: Form
Document No: CC-017-F01-01	Effective:

Complaint Number: _____ *(to be entered by QA)*

Complaint Received By:		Date Complaint Received: (MM/DD/YY)	
Brand Name:		Supplier:	
Lot Number:		Packaging Date:	
Name of Complainant:	Client Unique ID	Phone Number:	Email:
Description of Complaint:			
Complaint Sample: <input type="checkbox"/> Available <input type="checkbox"/> Not <input type="checkbox"/> Not Available <div style="text-align: center;">Requested</div>			
If a return sample is available for investigation, indicate date return package sent:			
Date forwarded to QA:			
Date Supplier Notified:			
QA Signature:			

Title: Product Return Letter	Doc. Type: Form
Document No: CC-017-F02-01	Effective:

Sunday, December 03, 2017

Attention:

Client Name
Address
City, Province
Tel:
Email:

Subject – <Product Name/Brand/Strain>

Dear <Client>,

Thank you for contacting Canada Inc., to report the product complaint for <Product name, brand, strain, Lot Number, Fill Size>. We are sending you this package, so that the product can be returned for an investigation.

Please place the product inside the enclosed bag and seal with tamper evidence tape provided. Place the bag inside the enclosed return envelope with this letter and send it to us via <Canada Post, Fedex> (return address is on the package).

Thank you for your interest in Canada Inc. products.

If you have any further questions, please do not hesitate to contact our Customer Service Department at <phone number> or <email>.

Kind Regards,

Customer Service
Canada Inc.

