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Reconsideration Process

Natural Health Products Directorate

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Canada

“Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

Natural Health Products Directorate

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1.0 Purpose of this Guidance Document

The purpose of this guidance document is to outline the manner in which the Natural Health Products Directorate (NHPD) administers sections 9, 10, 30 and 31 of the *Natural Health Products Regulations* (the Regulations). Such procedures will be referred to herein as the "Reconsideration Process".

It is the goal of the NHPD to attempt to resolve all disputes to which this Reconsideration Process may apply in a fair, transparent, and timely manner. The Reconsideration Process complements existing informal dispute resolution mechanisms at the NHPD such as discussions between the NHPD and applicants that may take place during the assessment of licence applications.

2.0 Reconsideration Process

2.1 Scope

The Reconsideration Process is available to applicants who want the NHPD to reconsider a decision to refuse to issue or amend a product or site licence. An applicant may submit a request that a decision be reconsidered to the NHPD for:

- Refusal to issue a Product Licence;
- Refusal to amend a Product Licence;
- Refusal to issue a Site Licence; and
- Refusal to amend a Site Licence.

The Reconsideration Process cannot be used by applicants to resolve the following:

- Disagreements regarding Departmental policies, guidelines or standards; and
- Disagreements related to changes in regulatory requirements resulting from the evolution of regulatory policy that may have resulted in other products reaching the market under less stringent or more favourable conditions.

The NHPD maintains other mechanisms to review and revise these situations which involve input from and consultation with a broad range of stakeholders. Where a request for reconsideration involves one of the two scenarios described above, the request will be denied.

2.2 Overview of the Reconsideration Process

The Reconsideration Process involves the review of the Directorate's decision within a process that is managed by the Director General of the NHPD or his or her delegate(s). The process aims to ensure a fresh look at the matter in the interest of fairness. Although the original application assessor may be consulted to clarify the basis of the original decision, the review is carried out by staff who did not undertake the original assessment. Exceptions may occur where the expertise related to the matter is highly specialized. The results of the review are presented to the Director General for reconsideration of the original decision.

Within thirty (30) calendar days of the date of the letter with the NHPD's decision, the applicant must submit a letter requesting that the decision be reconsidered. The letter should be sent to the attention of the Manager, Submission Management Division at the following address:

Bureau of Product Review and Assessment
2936 Baseline Road, Tower A, AL 3300C
Nepean, Ontario
K1A 0K9

Attn: Request for Reconsideration

Once the NHPD has acknowledged receipt of the request for reconsideration, the applicant must within twenty (20) calendar days of receipt of the NHPD's acknowledgement, the applicant must submit a comprehensive document to the NHPD, which outlines the applicant's position and includes full supporting information, cross-referenced to previously submitted data, as applicable (an electronic copy of this document, if available, should be provided as well). Should the applicant wish to meet with Directorate officials, this should be indicated when filing the comprehensive document. The purpose of this meeting is to allow the applicant to clarify his or her position. Neither the applicant's nor the NHPDs position will be debated nor will a reconsideration decision be made at this meeting.

The reconsideration will be based only on the information and material upon which the original decision was made. Any new information referenced or contained in the comprehensive document will not be taken into consideration and will be returned to the applicant for appropriate severances.

Within twenty (20) calendar days from the receipt of the applicant's supporting comprehensive document or from the date of the meeting if one is requested, the Director General will inform the applicant of the Directorate's decision to uphold or overturn the original decision. Where the Directorate upholds its decision to refuse to issue or amend a licence, a final notice that sets out the reason(s) for the refusal will be sent to the applicant. Where the Directorate's decision is overturned, a licence will be amended, issued or the application will be reinserted into the assessment process at the point it was at when the refusal was issued.

Appendix A – Sections 9 and 10 of the *Natural Health Products Regulations*

Refusal to Issue or Amend

9. (1) If the Minister refuses to issue or amend a product licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.

(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(a) give the applicant an opportunity to be heard in respect of the application; and

(b) reconsider the application after giving the applicant that opportunity.

10. (1) After reconsidering the application, the Minister shall issue or amend the product licence if the requirements of section 7 are met.

(2) If the Minister again refuses to issue or amend the product licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.

Appendix B – Sections 30 and 31 of the *Natural Health Products Regulations*

Refusal to Issue or Amend

30. (1) If the Minister refuses to issue or amend a site licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.

(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(a) give the applicant an opportunity to be heard in respect of the application; and

(b) reconsider the application after giving the applicant that opportunity.

31. (1) After reconsidering the application, the Minister shall issue or amend the site licence if the requirements of subsection 29(1) are met.

(2) If the Minister again refuses to issue or amend the site licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.