Submission Procedure

- Please complete ASC Clearance Submission Form, and submit it along with completed Checklist below, plus all required supporting documentation.
- ASC's Drug Clearance Section will evaluate submission to determine review scope and fee.
- ASC will inform submitter of applicable review fees and timeline, and request written authorization to proceed. ASC will proceed with review upon receipt of written authorization.
- Should ASC determine that external clinical review is required; the advertiser will be requested to provide written authorization in order for ASC to proceed.

Submission Requirements Checklist

Review Materials

- ☐ Therapeutic Comparative Advertisement
- ☐ Terms of Market Authorization[1] (for **ADVERTISED** and **COMPARATOR** product/ingredients)
- ☐ Current Labelling for both the **ADVERTISED** and the **COMPARATOR** products that is consistent with the terms of market authorization)
- ☐ Supporting Evidence (as per Directive and Guidance Document/SOPs)
- ☐ Promotional Materials relevant to proposed claim and campaign
- ☐ Explanation/justification of "Clinical Relevance[2]"

Additional Requirements (submit all those that are relevant)

- ☐ Attestation that results of supporting studies reflect "body of available evidence[3]" and have not been superseded by contradictory findings; **or** justification for any difference
- ☐ Attestation that Advertiser's Canadian product is identical to, or has no major changes (as per HPFB Policy *"Changes to Marketed New Drugs")* from the corresponding non-Canadian product used in original studies; **and**
- ☐ Advertiser has provided information to verify that the **COMPARATOR** product complies with TPD Policy: Canadian Reference Product; **or,**
- ☐ Attestation that Advertiser has verified that **COMPARATOR** product would not be subject to a bioequivalence study for premarket approval (as per TPD Guideline: Preparation of Drug Identification Number Submissions) and that **COMPARATOR** product meets criteria in Appendix II of Guidance Document
- ☐ Attestation that Advertiser has verified that Canadian and non-Canadian **COMPARATOR** products are bioequivalent, (as per current TPD Bioequivalence Policies and Guidelines - see Appendix I of Guidance Document)
- ☐ For product to product comparisons, attestation that Advertiser has verified that clinical studies were conducted and analysed according to principles embodied in ICH Guidelines: Structure and Contents of Clinical Trial Reports and Statistical Principles for Clinical Trials
- ☐ For side effect and safety comparison, attestation that Advertiser has readily available easy to understand patient information regarding the advertised product.

Authorization

- ☐ Authorization for ASC to access data from TPD relating to market approval for the **ADVERTISED** product

[1]TPD Definition: **Terms of market authorization** are comprised of information in the Product Monograph and the document that assigns a Drug Identification Number (DIN) (including related product labelling material and prescribing information) authorized by the TPD upon issuance of a DIN.
[2] TPD Definition: **Clinical Relevance** to the consumer refers to the practical value of the claim itself in assisting consumers to select an appropriate therapy. Practical value means offering a clinically significant benefit or advantage which can easily be understood and seen by the consumer when one treatment is compared to another, e.g., lack of side effect, ease of administration, faster onset of action, longer lasting relief, etc".
[3] TPD Definition: **Body of available evidence**: the information reasonably available as published or unpublished studies, other data in respected medical literature, generally available in the public domain at that point in time.