



**Pharmaceutical Advertising Advisory Board  
Conseil consultatif de publicité pharmaceutique**

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**Policy clarifications to help the PAAB help you.**

**1. PAAB Opinions Policy**

The PAAB has offered a written opinion service to help clients understand the PAAB code better, make good decisions and to provide direction during project development. See the fee schedule for details. Opinions can be requested:

- a. To clarify what is advertising subject to the regulations
- b. To clarify exemption from review
- c. To receive guidance on the acceptability of concepts
- d. To clarify linkage of material
- e. To receive guidance on the acceptability of references for product claims.
- f. To clarify contextual issues

As an unexpected result of PAAB review staff being helpful by providing multiple responses in some cases, a trend has evolved whereby clients have been routinely sending revisions, rebuttals, arguments etc to the PAAB, often by a multiple of letters. The requests for opinions end up resembling the review process where the PAAB will help get you to approval, where possible, even if it takes a multiple of letters. It ends up in time taken away from the reviewers and lessens PAAB review efficiency. The PAAB will enforce its original, and still standing policy of providing one opinion letter. If clarification is needed about anything written in that letter, the PAAB review staff will respond to requests by telephone. Generally 5-10 minutes should be all that is needed.

This clarification does not apply to opinions on final Direct-to-Consumer material going to market.

**2. Complete Submission Procedure**

PAAB Code section 8.1 (e)(ii) states "*Copies of all reference materials used in the APS. Sources of claims should be clearly identified and cross-referenced to the relevant part of the APS.*"

When clients do not follow this requirement, it slows down the review process and PAAB efficiency. Please change your internal policy to incorporate this activity when you prepare your PAAB submissions. Example: we are looking for claim A referenced to reference 1, page 2, section x and/or highlighted on the reference page. The PAAB is looking at a triage system that may bump those unmarked files to the back of the queue to allow us to serve clients that respect the requirements of the code. The PAAB is working on a standard marking system to be used by all clients. Consultation with the industry will occur before it becomes mandatory.

Ray Chepesiuk,  
PAAB Commissioner

*To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework. Fournir un service d'évaluation des renseignements soumis en vue d'une approbation qui favorisera une communication fiable et crédible sur les produits de soins de santé, et ce à l'intérieur du cadre réglementaire.*