

December 8, 2006

**Health Canada's Recommended Public Attestation Criteria
for Advertising Preclearance Agencies in Canada who provide review and
preclearance services of nonprescription drugs and natural health products
advertising material directed to consumers**

Agencies who want to provide review and preclearance services for nonprescription drug and natural health product (NHP) advertisements directed to consumers are requested to publicly attest to the criteria listed below.

Health Canada requests that when attesting to the criteria, each consumer advertising preclearance agency should post on its Website a *Statement of Qualifications* describing how and to what extent they meet each of the criteria so that industry can make informed choices when selecting their services.

Disclaimer:

Health Canada does not intend to review the statements of qualifications posted on the consumer advertising preclearance agencies' websites. Once notified by an agency that it meets the criteria, Health Canada will post the name of the agency on the Health Canada website with a disclaimer similar to this one. Inclusion of the name of an agency on Health Canada's Website will not be a recognition or an endorsement of the agency by Health Canada. This will only provide information to consumers and to industry as to which agencies have attested to meeting the criteria.

Caveat:

Health Canada is the national regulatory authority for health product advertisements.

Health Canada:

- provides policies to effectively regulate marketed health products,
- puts in place guidelines for the interpretation of the Regulations, and
- oversees regulated advertising activities.

Health product advertisements should not be false, misleading or deceptive. Health Canada will use a risk based approach in its compliance and enforcement activities.

Health Canada reserves the right to enforce the advertising provisions contained in federal legislation.

Public Attestation Criteria for Consumer Advertising Preclearance Agencies Recommended by Health Canada

1. Standard Recommended Requirements

1.1 The Consumer Advertising Preclearance Agency (the Agency) should possess and make publicly available in both official languages, the policies, procedures and standards it uses to ensure that the provided deliverables are in compliance with Health Canada's requirements as well as an annual reporting system of its preclearance activities of a nonproprietary nature related to consumer-directed advertising of nonprescription drugs and natural health products (NHPs).

1.2 The Agency should have in place processes for complaints resolution and adjudication and self-regulatory sanctions that include notification of required cases to Health Canada.

1.3 The Agency should have adequate performance evaluation and marketplace monitoring capacities.

2. Expertise

2.1 & 2.2 The Agency should possess the knowledge, skills and competencies required to successfully complete the full advertising preclearance function that includes the review and evaluation of therapeutic comparative claims for advertising purposes only and any subsequent advertising complaints, disputes and appeals associated with nonprescription drug and NHP advertising.

2.3 The Agency should possess the knowledge and experience necessary to address consumer environment, target audience and other advertising issues.

3. Corporate Relations

3.1 The Agency should possess mechanisms to communicate and partner with experts, stakeholders, media and government to adequately perform the preclearance function including complaints resolution.

Further detailed examples of how these criteria could be met are outlined in the following pages.

Additional Guidance on the Interpretation of the Public Attestation Criteria for Consumer Advertising Preclearance Agencies Recommended by Health Canada

1. Standard Recommended Requirements

1.1 Basics

- Written policies, procedures, and standards to ensure consistent, accurate and complete assessments of advertising materials consistent with the *Food and Drugs Act* and its Regulations, policies and guidelines and other Acts within the mandate of Health Canada. To foster accountability, transparency and accessibility, such policies, procedures and standards should be available on the Agency's website in both official languages.
- A process that provides for the use of only current Health Canada terms of market authorization {product licences for NHPs} as standards for advertising reviews.
- An appeal process for use by advertisers whose advertising copy submission has been rejected, in whole or in part.
- A seal/mark of advertising approval whose purpose is communicated to the public.
- A mechanism such as a Declaration of Competing Interests that demonstrates that the agency is an independent neutral body whose commercial, financial and other interests will not inappropriately influence decisions and judgement.
- An Annual Reporting System that includes a list of all preclearance activities undertaken for the year that is made available to the public.

1.2 Complaints & Sanctions

- An objective and timely complaints mechanism to accommodate complaints from the public, healthcare professionals and competitors regarding the therapeutic aspects of nonprescription drug and NHP advertising claims. The complaints procedure should be posted on the Agency's website in both official languages.
- An objective and timely complaints mechanism to accommodate competitor complaints regarding therapeutic comparative claims in nonprescription and NHP advertising.
- Meaningful self-regulatory sanctions that are proportional to the level and frequency of infraction and apply remedial measures, where appropriate, to obtain voluntary compliance.

- A process in place to refer to Health Canada complaints/issues where health and safety risks are identified, where it relates to advertising of unauthorized health products (unlicensed NHPs or unauthorized DIN products), cases of wilful non-compliance or where it relates to advertising of other health products such as prescription drugs to consumers.
- A system to post on the Agency's website in both official languages, reports of complaints in cases where complained-about advertising is found, after adjudication by the Agency, to be violative, as well as a listing of complaints referred by the Agency to Health Canada for adjudication.

1.3 Performance Evaluation & Monitoring Capacity

- A process in place to conduct a periodic performance evaluation (internal / external audit) as a system performance and quality check (percentage of compliance, evaluation of the timeliness of review, number of complaints, appeals, remedial actions, etc.). The results should be provided upon request to Health Canada, interested stakeholders and to members of the general public.
- A plan to routinely monitor that portion of the marketplace influenced by the preclearance advice provided by the agency as a post-publication, post-broadcast audit to evaluate level of compliance in all media (TV, radio, magazines, newspapers, Internet, outdoor advertising, targeted direct mail, messages from 1-800 lines, pamphlets and posters, etc.) with all regulatory requirements. Where there is a health or safety issue a process should be in place to refer the matter to Health Canada.
- A process in place to implement any new regulation, guideline, policy or initiative related to advertising of nonprescription drugs and NHPs, introduced by Health Canada or by industry where there is compliance with the *Food and Drugs Act* and its Regulations.

2. Expertise

2.1 Skills and Core Competencies

- Extensive expertise and competence in critical analysis of scientific information, and in the application and use of legislation, regulations, codes, policies, guidelines applicable to advertising of nonprescription drugs and NHPs.

- Independent / unbiased external consultants to provide any missing scientific expertise.
- Qualified personnel and proper documentation of their qualifications.

2.2 Product Expertise

- Wide knowledge of current clinical practice (pharmacy, medical, naturopathic field) of nonprescription drugs and NHPs along with their current and emerging scientific issues including any relevant product safety information.
- Review staff with extensive expertise in nonprescription drugs and natural health products.

2.3 Environment, Target Audience and Issues

- Extensive knowledge of consumer environment and expertise in consumer-based communications.
- Extensive knowledge of the target audience (consumers) level of understanding (comprehension including language, literacy, psychology and perception), needs and priorities in information needs.
- Extensive knowledge of consumer advertising issues (such as gender portrayal, advertising to sub-populations, violence, etc.).

3. Corporate Relations

3.1 Communications and Partnerships

- A mandate, scope of activities and requirements to enhance the voluntary submission of nonprescription drug and natural health product advertising material to the agency for preclearance review.
- Means to participate on and contribute to Health Canada's Advertising Preclearance Agencies Meeting Program. This will be struck by Health Canada and include representation from each Agency. A mechanism will be developed to ensure active participation in regulatory advertising initiatives, and consultations triggered by Health Canada.
- An agency advisory body that inputs to the agency's policies, procedures and standards, or access to an advisory body, with representation from appropriate stakeholder groups (health professionals, industry, pharmacy, media, consumers, etc.) where representatives are chosen to provide a balance of interests, where no single interest predominates to

ensure transparency and ongoing communications with all stakeholders. Representatives should disclose their Declarations of Competing Interests.

- A mechanism to foster partnerships with consumer and mass media (broadcast and print publishers), professional associations, advertising agencies, government and other stakeholders to ensure that only precleared advertising will be published or broadcasted.