Health Canada
Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

August 16, 2006

06-118281-52

CONSULTATION NOTICE

Re: Draft Attestation Criteria For Consumer Advertising Preclearance Agencies

On August 9, 2006, Health Canada announced its intention to make changes to the Consumer Advertising Preclearance System for nonprescription drugs and natural health products and to move forward with the posting of Attestation Criteria.

This Notice of Intent can be found on Health Canada's website at:
http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/pca-apa_noi-ai_e.html

Health Canada is moving away from endorsing consumer advertising preclearance agencies and is introducing a criteria-based system that will allow consumer advertising preclearance agencies to self-qualify. Health Canada is proposing draft attestation criteria to represent a minimal standard that agencies should meet to successfully perform in an advertising preclearance capacity. Agencies are being asked to attest to and demonstrate as part of a *Statement of Qualifications* how and to what extent they meet the recommended criteria and to post this information on their website. When an agency notifies Health Canada that this has been done, Health Canada will post the name of the agency on its website; however conformity with the criteria will remain the responsibility of the agency.

Health Canada remains the national regulatory authority for health product advertisements and reserves the right to enforce the advertising provisions contained in federal legislation.

Should you wish to provide comments on the draft criteria, you are requested to do so by September 15, 2006. The Marketed Health Products Directorate will consider any comments received by this date, in the finalization of the criteria. Your comments should be sent to:

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Public Attestation Criteria for Preclearance Agencies in Canada who provide review and preclearance services of nonprescription drugs and natural health products advertising material directed to consumers recommended by Health Canada

Agencies who want to provide review and preclearance services for nonprescription drug and natural health product (NHPs) 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 pre-clearance agency should post 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.

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.

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Attestation Criteria for Consumer Advertising Preclearance Agencies Recommended by Health Canada

1. Standard Recommended Requirements

1.1 The Consumer Advertising Preclearance Agency should possess and make publicly available the processes and advertising code of practice used to ensure that the provided deliverables are in compliance with Health Canada's requirements as well as an annual reporting system of all preclearance activities.

1.2 The Consumer Advertising Preclearance 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 Consumer Advertising Preclearance Agency should have adequate performance evaluation and marketplace monitoring capacities.

2. Expertise

2.1 & 2.2 The Advertising Preclearance Agency should possess the knowledge, skills and competencies required to successfully complete the preclearance function and any subsequent appeals associated with nonprescription drugs and natural health products (NHPs).

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

3. Corporate Relations

3.1 The Advertising Preclearance 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 Attestation Criteria for Consumer Advertising Preclearance Agencies Recommended by Health Canada

1. Standard Recommended Requirements

1.1 Basics

The Advertising Preclearance Agency should possess and have publicly available:

- Written procedures, processes, performance standards, policies and guidelines that ensure consistent, accurate and complete assessments of advertising materials.
- A well-defined agency code of advertising practices consistent with the *Food and Drugs Act* and its Regulations, policies and guidelines and other Acts within the mandate of Health Canada (HC).
- A process that provides for the use of only current HC terms of market authorization {product licences for natural health products (NHPs)} as standards for advertising reviews.
- 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

The Advertising Preclearance Agency should have:

- An internal dispute resolution / review process as a first route of complaints resolution.
- A timely, independent / unbiased appeals and complaints adjudication mechanism.
- Meaningful self-regulatory sanctions that are proportional to the level and frequency of code infraction and apply remedial measures, where appropriate, to obtain voluntary compliance.
- A process in place to refer to HC complaints/issues where health and safety issues are identified, where it relates to advertising of unauthorized health products (unlicenced NHPs), 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, reports of complaints and their outcomes which were subject to adjudication.

1.3 Performance Evaluation & Monitoring Capacity

The Advertising Preclearance Agency should have:

- 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 to interested stakeholders and to 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 and non-regulatory requirements. Where there is a health or safety issue a process should be in place to refer the matter to HC.

- A process in place to implement any new regulation, guideline, policy or initiative related to advertising of nonprescription drugs and natural health products, introduced by HC or by industry where there is compliance with the *Food and Drugs Act* and its Regulations.

2. Expertise

2.1 Skills and Core Competencies

The Advertising Preclearance Agency should have:

- 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, i.e, pharmacist

2.2 Product Expertise

The Advertising Preclearance Agency should have:

- Wide knowledge of current clinical practice (pharmacy, medical, naturopathic field) of nonprescription drugs and natural health products 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

The Advertising Preclearance Agency should have:

- 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

The Advertising Preclearance Agency should have:

- 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.

- An agency 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.

- Mechanisms to ensure active participation in regulatory advertising initiatives, and meetings triggered by HC.