

## NEW GUIDELINES ON LOOK-ALIKE SOUND-ALIKE NAMES FOR HEALTH PRODUCTS...

Catherine Daigle\*  
**LEGER ROBIC RICHARD, L.L.P.**  
Lawyers, Patent and Trademark Agents  
Centre CDP Capital  
1001 Square-Victoria – Bloc E – 8th Floor  
Montreal, Quebec, Canada H2Z 2B7  
Tel. (514) 987 6242 – Fax (514) 845 7874  
www.robic.ca – info@robic.com

Health Canada's new Guidance Document "Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names" has been in effect since January 1st, 2006 as an answer to various medical stakeholders' concerns. Thus, since the beginning of 2006, all drug submissions are subject to the Guidance's rules and regulations.

LA/SA names with spelling similarities and/or similar phonetics tend to create confusion for the Health Products and Food Branch (HPFB) in its review and analysis of a health product name. Furthermore, such names may constitute a tangible risk to Canadians' health by increasing the potential for errors in the prescription, dispensing or in the administration of a drug.

### **Health product names: how to avoid confusion**

The new Guidance therefore applies to all health products, including pharmaceutical and biological products, prescribed drugs and over-the-counter products, medical devices, natural health products and veterinary drugs.

In accordance with the *Food and Drug Regulations*, a drug's name must be provided with the submission of a drug to the HPFB for approval as part of the information required to assess the safety and effectiveness of a product. Additionally, the Guidance now requires that all proposed brand names submitted for review must be examined to ensure that they are unlikely to cause medication errors with other brand names and/or generic names.

---

© CIPS, 2006.

\* Of LEGER ROBIC RICHARD, L.L.P., a multidisciplinary firm of lawyers, and patent and trademark agents. Published in the Fall 2006 issue (Vol. 10, No. 4) issue of our Newsletter. Publication 068.077E.

Indeed, sponsors should pay careful attention to LA/SA similarities with products that are currently on the market in order to prevent potential errors. In short, the Guidance aims to prevent and curb specific practices related to LA/SA health product names, including the following:

- similar brand name designations;
- use of similar or identical abbreviations and suffixes;
- brand name designations similar to generic names;
- resorting to the extension of a line of product (*i.e.* when a drug is named by using the brand name of another drug, and simply adding to or modifying the prefix or suffix with the intent of distinguishing the new product from the original.)

### **Health Canada's Guidance application**

If, during the drug review process, the HPFB identifies a potentially confusing name, it may be disallowed and consequently, the proposed product will be issued a Notice of Compliance (NOC) or a Notice of Non-compliance (NON), as applicable depending on the following:

- if the brand name is at issue, a NOC will be issued without the brand name;
- if the issue is related to the proper name, which is defined as the assigned name of a particular drug or the common name (*i.e.* the usual name under which a particular drug is known), then a NON will be issued, since a health product's Notice of Conformity cannot be issued without the related proper or common name.

In order to avoid the issuance of an "incomplete" NOC, or worse, a NON pursuant to a drug review, a cautious sponsor will provide the HPFB with a prioritized list of name choices (maximum of two). Should the first name chosen be rejected, the subsequent name on the list would then be assessed. In addition, the sponsor should also submit a risk assessment and an evaluation of the product's proposed brand name which would be supported by studies, data and analysis.

In a world of ever evolving scientific discoveries of new techniques of assessment, we can hardly hope, however, for the development of a foolproof technology that would allow us to prevent mistakes linked to LA/SA names. Nevertheless, an evaluation of the risks may include but would not be limited to the following elements: search for similar proprietary and non-proprietary brand names; computer analysis of both spelling and phonetic similarities; verbal and handwritten prescription testing studies; review of medication errors (for example, regarding dosage form or administration); and, finally, process flow studies, from the time of purchase to administration.

During the drug name review, the HPFB will more particularly consider the following criterion:

- the marketing status of the product, whether it is a prescribed drug or self-care health product;
- the therapeutic category;
- the indications and/or directions for use;
- the clinical setting for distribution or use of a drug;
- the packaging, the labelling and the storage of the health product;
- the strength;
- the dosage form or methods of administration;
- the proposed dosage and dosing interval;
- groups of similar patients.

Similarly, during the review of an off-the-shelf health product, the HPFB will also take into consideration the retail placement of the product, while giving less consideration to other criteria such as strength and dosage form.

In conclusion, Health Canada's application of the new Guidance which considers the specific safety issues linked to the LA/SA names is henceforth an essential guide for professionals of the healthcare industry, who will now be able to use such tool to assist them in complying, more efficiently, with applicable policies and legislation.

**ROBIC** + LAW  
+ BUSINESS  
+ SCIENCE  
+ ART

