Health Canada Santé Canada

April 2, 2013

Notice

Our file number: 13-103438-115

Classification of Non-medicated Eyewashes

Purpose

Classification of a therapeutic product determines whether it is regulated as a drug [that is (i.e.) pharmaceutical, biologic, natural health product] or a medical device. The purpose of this notice is to communicate Health Canada's current decision that non-medicated eyewashes should be regulated under the *Natural Health Products Regulations* (NHPR). This notice does not apply to medicated eyewashes.

This notice outlines the principles and considerations to be applied in determining whether non-medicated eyewashes are drugs or medical devices. It has been created and published to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. This notice also provides assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent, and effective. It is intended to be used in conjunction with other existing guidance documents and policies.

Rationale for Classification of Eyewashes as Natural Health Products

Non-medicated eyewashes fall within the definition of drug in section 2 of the *Food and Drugs Act* because they are a mixture of substances used in the treatment of an abnormal state. When intended for human use, they fall within the definition of natural health product (NHP) because their medicinal ingredient, purified water, is a natural substance captured by Item 2 in Schedule 1 to the NHPR. Health Canada considers substances added to the solution to establish the pH, or to buffer or preserve the solution to be non-medicinal ingredients.

Manufacturers who are seeking market authorization for non-medicated eyewashes should obtain a Natural Product Number (NPN) and a site licence. Guidance on obtaining market authorization and a site licence under the NHP regulatory framework can be found on Health Canada's website (http://web.hc-sc.gc.ca/dhp-mps/prodnatur/applications/index-eng.php).

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Transition of Marketed Non-medicated Eyewashes to NHP Regulatory Framework

This notice does not indicate a determination on the classification of a particular product. Manufacturers of non-medicated eyewashes holding a medical device licence have been notified that they will be given the opportunity to make representation to Health Canada on the classification of their products. Health Canada will make a determination on classification only after hearing these representations. If the Department determines that these products should be licensed as NHPs, Health Canada will assist in the transition to the NHP regulatory framework.

Additional Information

For more information regarding the classification of a therapeutic product as either a drug or device, please refer to the *Guidance Document: Factors Influencing the Classification of Products at the Device-Drug Interface*.

The Therapeutic Products Classification Committee (TPCC) makes recommendations on the classification of a product as either a drug (pharmaceutical, biological, or NHP), medical device, or combination product. The TPCC Secretariat performs administrative tasks associated with the work of the committee such as the communication of classification recommendations.

For questions regarding the content of this notice please email the TPCC Secretariat at: Drug-Device.Classification.Drogue-Instrument@hc-sc.gc.ca.