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Product Assessment Against Criteria: Diaper Rash Products

Classification: Drug

Date of Decision: Spring 2009

Summary of Classification:

Diaper rash is recognized as an abnormal state of the skin requiring therapeutic intervention. As such, any product claiming treatment or prevention of diaper rash will be classified as a drug.

Evaluation Against Criteria

Representation:

Is the product represented in a manner suggesting it is used for treating, diagnosing, preventing, or curing disease or restoring, correcting or modifying organic functions in human beings?

A diaper rash, also known as irritant diaper dermatitis, is characterized by erythema and scaling of the skin in the diaper area, and can occur in children and adults. It develops when the stratum corneum breaks down as a result of exposure to prolonged wetness and an increased skin pH

caused by urine and feces. In adults, the stratum corneum is composed of 25 to 30 layers of flattened dead keratinocytes, which are continuously shed and replaced from below. These dead cells are interlaid with lipids secreted by the stratum granulosum just underneath, which help to make this layer of the skin a waterproof barrier. The stratum corneum's function is to reduce water loss, repel water, protect deeper layers of the skin from injury and repel microbial invasion of the skin. In infants, this layer of the skin is much thinner and more easily disrupted. Diaper dermatitis can be complicated by secondary bacterial or fungal infection, or can be the result of seborrheic and/or atopic dermatitis.

Is the product likely to be understood by consumers to have characteristics of a drug?

Diaper rash creams are used solely for the prevention or treatment of an abnormal skin state and/or the alleviation of the resultant. Diaper rash products are not used for aesthetic or cosmetic purposes.

Composition:

Does the product's composition suggest it is an agent for treating, diagnosing, preventing, or curing disease or restoring correcting or modifying organic functions in human beings?

Diaper rash products contain ingredients frequently used in cosmetic as colourants or humectants (e.g. zinc oxide, allantoin, petrolatum, etc.) The ingredients in the products are not necessarily therapeutic until applied at appropriate concentrations and with the intent to treat or prevent an abnormal skin state such as diaper dermatitis or other medical condition.

Level of action:

Does the product exert solely a superficial effect?

The product is applied topically with no evidence of percutaneous absorption. The effect of the product is to treat and remove an abnormal and irritated skin condition, so its effect cannot be considered transient.

Other considerations:

In the United States, New Zealand, and Australia diaper rash products are classified as drugs. In the European Union, they are either cosmetics or drugs depending on whether a therapeutic treatment claim is made.

Conclusion:

The primary purpose of diaper rash products is to treat and prevent an abnormal skin condition which can result in infection and scarring if not treated properly. Based on these factors, diaper rash products meet the definition of 'drug' under the *Food and Drugs Act*, and are regulated under the *Natural Health Product Regulations* or *Food and Drug Regulations* depending on ingredient.

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