ANTI-DANDRUFF PRODUCTS

Date: October 12, 2006

Anti-dandruff products are classified as natural health products (NHPs) if they contain ingredient(s) from Table 1. Applicants applying for a natural product number (NPN) can access the appropriate forms and guidance at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html

Anti-dandruff products are classified as drugs if they contain an ingredient from Table 2. Applicants applying for a drug identification number (DIN) can access the appropriate forms and templates at: http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index_e.html

Table 1: NHP medicinal ingredients

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salicylic acid (Gottschalck and McEwen 2006; USP 29; O’Neil et al. 2001)</td>
<td>Salicylic acid (Gottschalck and McEwen 2006; USP 29; O’Neil et al. 2001)</td>
<td>Salicylic acid* (Gottschalck and McEwen 2006; USP 29; O’Neil et al. 2001) CAS No. 000069-72-7</td>
<td>1.8 - 3.0% (FDA 1991)</td>
</tr>
<tr>
<td>2-hydroxybenzoic acid (Gottschalck and McEwen 2006; O’Neil et al. 2001)</td>
<td>2-hydroxybenzoic acid (Gottschalck and McEwen 2006; O’Neil et al. 2001)</td>
<td>2-hydroxybenzoic acid (Gottschalck and McEwen 2006; O’Neil et al. 2001)</td>
<td>0.5 - 2.5% (Sweetman 2002)</td>
</tr>
<tr>
<td>Selenium sulfide (Gottschalck and McEwen 2006; USP 29)</td>
<td>Selenium sulfide (Gottschalck and McEwen 2006; USP 29)</td>
<td>Selenium sulfide* (Gottschalck and McEwen 2006; USP 29) CAS No. 007488-56-4</td>
<td>2 - 5% (FDA 1991)</td>
</tr>
</tbody>
</table>

* Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Compendium of Monographs) or requires citation of an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File’s registered owner.

† The CAS number may be provided as additional information.

Table 2: Drug medicinal ingredients

<table>
<thead>
<tr>
<th>Medicinal ingredient preferred name</th>
<th>Synonyms and other recognized names</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coal tar</td>
<td></td>
<td>0.5 - 10.0%</td>
</tr>
<tr>
<td>Pyrithione zinc</td>
<td></td>
<td>0.1 - 2.0%</td>
</tr>
</tbody>
</table>

1Pyrithione zinc is permitted at concentrations of 1-2% in products intended to be applied and rinsed off after brief exposure and permitted at concentrations of 0.1 - 0.25% in products intended to be applied and left on the scalp.
Route(s) of administration: Topical (FDA 1991)

Dosage form(s): Those that are suited to the allowable route of administration and are established scientifically recognized dosage forms.

Use(s) or Purpose(s):
Statement to the effect of:
- For the relief of (controls, helps prevent, and/or reduces the recurrence of) dandruff and/or the symptoms (itching, irritation, redness, flaking and/or scaling) associated with dandruff (FDA 1991)

Dose(s):

Subpopulation: Subpopulation does not need to be specified.

Quantity: See Tables 1 and 2.

Permitted combinations: The only permitted combination is salicylic acid and sulfur (Gupta and Nicol 2004):
- Salicylic acid: 1.8 - 3.0% + Sulfur: 2 - 5%

Directions for use:
Statement(s) to the effect of:

For products formulated to be applied and rinsed off (shampoos and rinses):
- Apply evenly to scalp, leave on for several minutes, and then rinse off. (Optional: repeat application) (Sweetman 2002).
- Use at least twice per week or as directed by a health care practitioner (FDA 1991).

For products formulated to be applied and left on:
- Apply to scalp one to four times daily or as directed by a health care practitioner (FDA 1991).

Duration of use: No statement is required.

Risk information:
Statement(s) to the effect of:
Cautions and warnings:

For all products:
- For external use only (Sweetman 2002; FDA 1991).
- Avoid contact with eyes. If contact occurs, rinse thoroughly with water (FDA 1991).
- Consult a health care practitioner if condition worsens or does not improve after regular use of this product (FDA 1991).
- Consult a health care practitioner prior to use in children under 2 years of age (Berardi et al. 2002).

Contraindications:

For products containing selenium sulfide:
- Do not use within 48 hours of applying hair colours or permanent waving preparations (Sweetman 2002; Carruthers-Czyzewski et al. 1996).

Non-medicinal ingredients: The International Nomenclature for Cosmetic Ingredients (INCI) will be accepted.

For products containing Table 1 medicinal ingredients:
Ingredients must be chosen from the current NHPD List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Other ingredients currently accepted as cosmetic ingredients will also be considered.

Specifications: This monograph describes those requirements that are specific to this class of drugs and to natural health products (NHPs).
Note that requirements described in the Regulations to the Food and Drugs Act must be met.

Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the monograph.

For products containing Table 1 medicinal ingredients only:
Products must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.
References:


