ACNE THERAPY

Date: October 12, 2006

Acne therapies are classified as natural health products (NHPs) if they contain ingredients 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

Acne therapies are classified as drugs if they contain benzoyl peroxide. Applicants applying for a drug identification number (DIN) can access the appropriate forms and guidance at:
http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index_e.html

Table 1: NHP medicinal ingredients

Proper name(s)	Common name(s)	Source material(s)	Quantity
Salicylic acid (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001) **2-Hydroxybenzoic acid** (Gottschalck and McEwen 2006; O'Neil *et al.* 2001)	**Salicylic acid** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001)	**Salicylic acid*** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001) CAS No. 000069-72-7[+]	**0.5 – 2.0 %** (FDA 2005)
Sulfur (Gottschalck and McEwen 2006; USP 29; O'Neil *et al*. 2001)	**Sulfur** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al*. 2001)	**Sulfur*** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al*. 2001) CAS No. 007704-34-9[+]	**3 – 10 %**[1] (FDA 2005)
1,3-Benzenediol (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001) **Resorcinol** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001)	**Resorcinol** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001)	**Resorcinol*** (Gottschalck and McEwen 2006; USP 29; O'Neil *et al.* 2001) CAS No. 000108-46-3[+]	**2 %**[2] (FDA 2005)
1,3-Benezenediol, monoacetate (Gottschalck and McEwen 2004; USP 29) **Resorcinol monoacetate** (USP 29; O'Neil *et al.* 2001)	**Resorcinol monoacetate** (USP 29; O'Neil *et al.* 2001)	**Resorcinol monoacetate*** (USP 29; O'Neil *et al.* 2001) CAS No. 000102-29-4[+]	**3 %**[2] (FDA 2005)

*Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Compendium of Monographs) or requires a 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.
[1]The appropriate dosage range for sulfur in combination with resorcinol or resorcinol monoacetate is 3-8 % (FDA 2005).
[2] Resorcinol and resorcinol monoacetate are not permitted as single medicinal ingredients and must be in combination with 3-8 % sulfur (FDA 2005).

Table 2: Drug medicinal ingredients

Medicinal ingredient preferred name	Synonyms and other recognized names	Quantity
Benzoyl peroxide		**2.5 – 5.0 %**

Route(s) of administration: Topical

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(s) to the effect of:

For all products:
- Helps treat acne pimples (**Optional: "**and allow skin to heal") (FDA 2005).
- Dries and helps clear up acne pimples (**Optional: "**and allow skin to heal") (FDA 2005).
- Reduces the number and/or severity of acne pimples (**Optional: "**and allow skin to heal") (FDA 2005).
- Penetrates pores to help control (reduce) acne pimples (FDA 2005).
- Helps keep skin clear of new acne pimples (FDA 2005).
- Helps prevent new acne pimples from forming (FDA 2005).

For products containing benzoyl peroxide the following statement may be made:
- Prevents and kills acne bacteria

Unacceptable use(s) or purpose(s):

Statement(s) to the effect of:

- Controls oil (oily skin).
- Cures acne.

Dose(s):

Subpopulation:	Subpopulation does not need to be specified.
Quantity:	See Tables 1 and 2.
Permitted combinations:	The only permitted combinations are sulfur + resorcinol or resorcinol monoacetate (FDA 2005): Sulfur: 3 – 8 % + Resorcinol: 2 % Sulfur: 3 – 8 % + Resorcinol monoacetate: 3 %
Additional notes:	Products containing resorcinol or resorcinol monoacetate in combination with sulfur can not be indicated as body cleansers (FDA 2005).

Directions for use:

Statement(s) to the effect of:

For products containing salicylic acid, sulfur, resorcinol or resorcinol monacetate which are intended to be applied to the skin and left on (i.e. cream, ointment, etc.) (FDA 2005):

1. Cleanse skin thoroughly before applying the product.
2. Apply product to affected areas one to three times daily or as directed by a health care practitioner.
3. **Optional:** Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed. If dryness or peeling occurs, reduce application to once a day or every other day.
4. **Optional:** Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first three days. If no irritation occurs, follow the directions outlined in steps one to three.

Note: There are no specific statements required for products containing salicylic acid, sulfur, resorcinol or resorcinol monacetate which are intended to be applied to the skin and rinsed/peeled off (i.e. cleanser, mask, etc.) (FDA 2005).

For products containing benzoyl peroxide:

1. Wash hands with non-medicated soap (contains no benzoyl peroxide).
2. Apply twice daily or as directed by a health care practitioner.
3. Fair-skinned individuals should begin with one application.
4. For more severe cases, and/or if substantial improvement is not apparent within 3-4 weeks, consult a health care practitioner.

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 (FDA 2005).
- Using other topical acne products at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one product should be used unless directed by a health care practitioner (FDA 2005).
- Avoid contact with eyes; if contact occurs, rinse thoroughly with water (Berardi *et al*. 2002; Sweetman 2002).
- Discontinue use if excessive skin irritation develops or increases. If irritation persists, consult a health care practitioner (Berardi *et al*. 2002; Sweetman 2002).

For products containing benzoyl peroxide:

- Avoid contact with lips, mouth, and nostrils; if contact occurs, rinse thoroughly with water.
- This product may bleach hair or dyed fabrics.

For all products containing the non-medicinal ingredient(s) alpha-hydroxy acids (AHA) at concentrations ranging from 3-10% and/or retinol at concentrations ranging from 0.1-1.0%:

- "This product contains [*insert as appropriate:* an alpha-hydroxy acid (AHA) and/or retinol] that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Please limit sun exposure and apply a sunburn protectant while using this product and for a week afterwards."

Contraindications:

For all products containing resorcinol or resorcinol monoacetate in combination with sulfur:

- Do not use on broken skin (FDA 2005).
- Do not apply to large areas of the body (FDA 2005).

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:
Products must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.

References:

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

FDA 2005: USA Department of Health and Human Services: Food and Drug Administration, 2005. 21 CFR Part 333. Topical Anti-Microbial Drug Products for Over-the-Counter Human Use, Final Monograph. [Accessed 2006-01-09]. Available at: www.fda.gov/cder/otcmonographs/Acne/acne(333D).pdf

Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook. 11th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2006.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th edition. Whitehouse Station (NJ): Merck and Co., Inc; 2001.

Sweetman SC, editor. Martindale: The Complete Drug Reference. 33rd edition. London (UK): Pharmaceutical Press; 2002.

USP 29: The United States Pharmacopeia and the National Formulary (USP 29/NF 24). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2006.