LEMON BALM

Date: March 17, 2008

Proper name(s): *Melissa officinalis* L. (Lamiaceae) (USDA 2001)

Common name(s): Lemon balm, melissa (USDA 2001)

Source material(s): Aerial parts (EMEA 2007)

Route(s) of administration: Oral (EMEA 2007)

Dosage form(s): Those suited to the allowable route(s) of administration. This monograph is not intended to include food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s): Statement(s) to the effect of:

- Traditionally used in Herbal Medicine as a sleep aid (in cases of restlessness or insomnia due to mental stress) (EMEA 2007).
- Traditionally used in Herbal Medicine to help relieve digestive disturbances, such as dyspepsia (EMEA 2007).

Dose(s):

Subpopulation: Adults and adolescents, ≥ 13 years (EMEA 2007)

Quantity: Preparations equivalent to 0.4-13.5 g dried aerial parts, per day (EMEA 2007)

See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.
Duration of use:  
No statement required.

Risk information:  
Statement(s) to the effect of:

Caution(s) and warning(s):

Sleep aid:  
Consult a health care practitioner if sleeplessness persists continuously for more than 3 weeks (chronic insomnia) (Berardi et al. 2002; Dipiro et al. 2002).

All uses:

- Consult a health care practitioner if symptoms persist or worsen.
- Consult a health care practitioner prior to use if you are pregnant or breastfeeding (EMEA 2007).
- Consumption with alcohol, other medications or health products with sedative properties is not recommended (EMEA 2007).

Contraindication(s):  
No statement required.

Known adverse reaction(s):  
Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness (EMEA 2007).

Non-medicinal ingredients:  
Must be chosen from the current NHPD List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications:

- The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.
- The medicinal ingredient may comply with the specifications outlined in the Lemon Balm Monograph published in the British Pharmacopoeia or the Melissa Leaf Monograph published in the European Pharmacopoeia.

References:


Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use (EMEA 2007)

Dried aerial parts: 1.5-4.5 g, 1-3 times per day

Infusion: 1.5-4.5 g dried aerial parts, 1-3 times per day

**Directions for use:** Pour 150 ml of boiling water over dried aerial parts and infuse for 5-15 minutes.

Fluidextract: 2-4 g dried equivalent, 1-3 times per day
(1:1, 45% ethanol, 2-4 ml)

Tincture: 0.4-1.2 g dried equivalent, 1-3 times per day
(1:5, 45% ethanol, 2-6 ml)