Date: December 7, 2006

Proper name(s): Melatonin (Sweetman 2002) or N-acetyl-5-methoxytryptamine (Buscemi et al. 2004)

Common name(s): Melatonin, Pineal hormone (O'Neil 2001)

Source material(s): Synthetic (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)

Pineal gland of non-human animals (Buscemi et al. 2004) other than those susceptible to Transmissible Spongiform Encephalopathy (TSE) diseases including Bovine Spongiform Encephalopathy (BSE) (NHPD LC IAS 2006)

Route(s) of administration: Oral or sublingual (Buscemi et al. 2004)

Dosage form(s): Those suited to the allowable route(s) of administration.

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

- Helps increase the total sleep time (aspect of sleep quality) in people suffering from sleep restriction or altered sleep schedule, e.g. shift-work and jet lag (Buscemi et al. 2004; Zhdanova et al. 2001; Shamir et al. 2000; Skene et al. 1999; Brusco et al. 1999; Sanders et al. 1999; Dolberg et al. 1998; Suhner et al. 1998b; Garfinkel et al. 1995; Haimov et al. 1995; Petrie et al. 1993; Claustat et al. 1992; Sack et al. 1991; Petrie et al. 1989).

- Helps relieve the daytime fatigue associated with jet lag (Buscemi et al. 2004).

- Helps to reduce the time it takes to fall asleep (sleep onset latency aspect of sleep quality) in people with delayed sleep phase syndrome (Buscemi et al. 2004).

- Helps re-set the body’s sleep-wake cycle (aspect of the circadian

**Dose(s):**

**Subpopulation:** Adults only (IOM 2004)

**Quantity:**


**Duration of use:** For use beyond 4 weeks, consult a health care practitioner (Buscemi et al. 2004; IOM 2004).

**Risk information:** Statements to the effect of:

**Cautions and warnings:** Consult a health care practitioner prior to use if you have a hormonal disorder, diabetes, liver or kidney disease, cerebral palsy, seizure disorders, migraine, depression and/or hypertension or if you are taking blood pressure or sedative/hypnotic medications (IOM 2004; Ninomiya et al. 2001; Cagnacci et al. 2001; Lusardi et al. 2000; Carman et al. 1976).

If symptoms persist continuously for more than 4 weeks (chronic insomnia), consult your health care practitioner (Dipiro et al. 2002).

**Contraindications:** Do not use if you are taking immunosuppressive drugs (Lissoni et al. 1999).

Do not drive or use machinery for 5 hours after taking melatonin (Avery et al. 1998).

Do not use if you are pregnant or breastfeeding (IOM 2004).
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: Must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.

References:


