M E M O R A N D U M DEPARTMENT OF HEALTH AND HUMAN

SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND

RESEARCH

DATE: September 10, 2014

FROM: Jing Zhang, MD. PhD.

Medical Team Leader, Division of Psychiatry Products

HFD-130

SUBJECT: Medical Team Leader Review

NDA/Supp#: 21336/S-005, S-010

Proprietary/

Established name: Emsam (selegiline transdermal system)

Dosage forms/

Strength: 6 mg/24 hours (20 mg/20 cm2), 9 mg/24 hours (30 mg/30 cm2) and

12 mg/24 hours (40 mg/40 cm2) transdermal systems

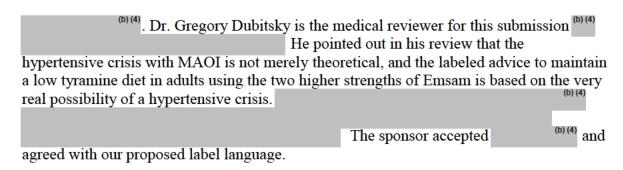
Indication: Major Depressive Disorder

Recommendation: Approval

Emsam is a transdermal patch formulation of selegiline, a non-selective, irreversible monoamine oxidase inhibitor (MAOI). Emsam is approved by FDA for the treatment of major depressive disorder in adults in doses of 6, 9, and 12 mg per 24 hours applied daily.

Supplement S-005 provided for the conversion of Emsam labeling to PLR format. Supplement S-010 contained the safety and efficacy data from Study S9303-P0605, a study of Emsam in adolescent patients (ages 12-17) with major depressive disorder which is a postmarketing commitment at the time of original NDA approval. Even though we felt that Study S9303-P0605 fulfilled the PMC during the first review cycle, a Complete Response letter was issued on Feb. 3, 2014 for both supplements because we did not reach agreement with the sponsor on the product labeling.

The sponsor resubmitted these supplements with revised labeling. In the resubmission, the sponsor agreed that EMSAM should be contraindicated in children under 12 years as we recommended.



At this time, I will recommend the division take approval action on these two supplements.

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/s/

JING ZHANG
09/10/2014

MITCHELL V Mathis 09/10/2014