DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021336/S-005/S-010
NDA 021708

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Somerset Pharmaceuticals, Inc.
Attention: Juliane M. Foley, MSA, RAC
Senior Manager, Regulatory Affairs
781 Chestnut Ridge Road, P. O. Box 4310
Morgantown, WV 26504–4310

Dear Ms. Foley:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 26, 2009 (21336/S-005) and April 3, 2013 (21336/S-010), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EMSAM (Selegiline Transdermal System) 6 mg/24 hours, 9 mg/24 hours, and 12 mg/24 hours.

We acknowledge receipt of your amendments dated July 10, 2014, and July 28, 2014.

The July 10, 2014, submission constituted a complete response to our February 3, 2014, action letter.

These "Prior Approval" supplemental applications provide for the following changes to product labeling:

21336/S-005
Conversion of the EMSAM prescriber information (PI) to the Physician Labeling Rule (PLR) format.

21336/S-010
Required pediatric postmarketing study report for the use of EMSAM in the treatment of major depressive disorder in adolescents (ages 12 through 17).

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 6 years old in the treatment of major depressive disorder, because studies are highly impractical due to the low prevalence of this disorder in this age range.

We are waiving the pediatric study requirement for ages 7 to 11 years old in the treatment of major depressive disorder, because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric group. The reason for granting the waiver is that some children will likely

require selegiline levels that mandate tyramine restrictions and the reliability of children in adhering to a low tyramine diet is questionable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

FULFILLMENT OF POSTMARKETING REQUIREMENT

Your submission of April 3, 2013 contained the final report for the following postmarketing requirement listed in the February 27, 2006 approval letter to NDAs 21336 and 21708.

1116-1 You are required to assess the safety and effectiveness of EMSAM as a treatment for Major Depressive Disorder in pediatric patients ages 7 to 17 (children and adolescents). Both children (ages 7 to 11) and adolescents (ages 12 to 17) should be equally represented in the samples, and there should be a reasonable distribution of both sexes in these age strata.

On May 15, 2006, you requested to waive studies in children ages 7 to 11 years because of potential safety concerns in this population. FDA agreed with your argument and granted a partial waiver for the 7 to 11 year age group on October 17, 2006.

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes all your postmarketing requirements and postmarketing commitments acknowledged in our February 27, 2006, letter.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Additionally, we remind you that NDA 21708 is administratively closed. Therefore, all 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21336 for this drug product. In the future, do not make submissions to NDA 21708.

If you have any questions, contact CDR Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at (301)796-4158 or email: Kofi.Ansah@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell Mathis, M.D.
CAPT USPHS
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
09/10/2014