NDA 21-875 - NUVIGIL® (armodafinil) Tablets [C-IV]

Cephalon, Inc.
41 Moores Road, Frazer, Pennsylvania 19355, USA

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I GOAL

To inform healthcare providers about the risk of serious skin rash and other hypersensitivity reactions, particularly in pediatric patients, treated with NUVIGIL.

To inform patients about the serious risks associated with NUVIGIL.

II REMS ELEMENTS

A Medication Guide

A Medication Guide will be dispensed with each NUVIGIL prescription. Cephalon will institute the following measures to comply with the applicable requirements of 21 CFR 208.24:

1. Each packaging configuration of NUVIGIL will include the Medication Guide(s). Pharmacy trade bottles will have multiple Medication Guides attached. Each unit-of-use physician sample package will contain a single Medication Guide.
2. Pharmacy trade container labels will prominently state that the product is to be dispensed with a Medication Guide. Unit-of-use physician sample packages will have a prominent instruction for the patient to read the Medication Guide before taking the product.
3. Medication Guides will be provided upon request through the toll-free Medical Services information line at Cephalon.
4. Medication Guides will be available to healthcare professionals through sales representatives.

Please see appended Medication Guide.

B Communication Plan

Cephalon will implement a communication plan to healthcare professionals to support implementation of this REMS:

1. The audience for this communication plan will include practitioners who are likely to prescribe NUVIGIL (e.g., sleep medicine specialists, pulmonary disease specialists, neurologists, psychiatrists, primary care physicians, selected pediatric prescribers, and non-physician prescribers [nurse practitioners and physician assistants]) and pharmacists.

2. Cephalon will provide prescribers and pharmacists with the educational materials listed below:

    a. Prescriber Materials – Dear Healthcare Professional Letter
       Prescriber Brochure
    b. Pharmacist Materials – Pharmacist Action Letter
    c. Additional Resources – REMS Program Internet Site

    The printed materials listed above are appended.

3. Distribution of materials:

    a. There will be a one-time distribution of the Dear Healthcare Professional Letter sent within 4 weeks of REMS approval.

    b. The Prescriber Brochure will be sent within 60 days of REMS approval. Cephalon will monitor product prescribing at the end of the initial 6-month period following REMS approval. Any healthcare professionals who have prescribed PROVIGIL or NUVIGIL during this time and who are not identified in the initial prescribing audience will be mailed a copy of the Prescriber Brochure. Cephalon field sales representatives will also have a supply of Prescriber Brochures to provide to prescribers. There will be a one-time distribution of the Prescriber Brochure through field sales representatives to all targeted HCPs who receive an in-person product detail, and a one-time distribution to any newly targeted HCPs who receive an in-person product detail for a period of 3 years following REMS approval. Sales representatives will stop distributing the Prescriber Brochure 3 years after REMS approval.

    c. There will be a one-time distribution of the Pharmacist Action Letter sent within 60 days of REMS approval.

Cephalon will implement a stand-alone link entitled, "Important Information about Serious Rash", on the product websites within 60 days following REMS approval. The link will direct users to a separate website that describes the REMS program and provides a copy of the Dear Healthcare Professional Letter, Prescriber Brochure, Full Prescribing Information, and Medication Guides. The website page is appended.

C Elements to Assure Safe Use

This REMS does not include other elements to assure safe use.

D Implementation System

Because this REMS does not include other elements to assure safe use, an implementation system is not necessary.

E Timetable for Assessment of the REMS

Cephalon will submit REMS assessments to the FDA annually for the first 3 years and at 7 years from the date of approval of the REMS. To facilitate inclusion of as much

information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Cephalon will submit each assessment so that it will be received by the FDA on or before the due date.