



NDA 11-961 / S-039

Validus Pharmaceuticals  
Attention: James R. Hunter  
2001 Route 46, Suite 310  
Parsippany, NJ 07054

Dear Mr. Hunter:

Please refer to your supplemental new drug application dated June 29, 2007, received July 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Marplan (isocarboxazid) Tablets.

Refer also to the Agency letter of May 1, 2007, requesting revisions to your prescriber labeling and Medication Guide based upon the December 13, 2006 meeting of the Psychopharmacologic Drugs Advisory Committee.

Reference is also made to an e-mail communication from the Agency dated July 11, 2007, requesting additional revisions to the labeling, and your e-mail of July 17, 2007, accepting these changes.

This new drug application, submitted as "Changes Being Effected" provides for the following revisions to labeling:

1. Revisions to the Black Box entitled **Suicidality and Antidepressant Drugs** at the beginning of the prescriber labeling.
2. Revisions to the **WARNINGS-Clinical Worsening and Suicide Risk** section.
3. Revisions to the **PRECAUTIONS-Information for Patients** section.
4. Revisions to the **MEDICATION GUIDE**.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl/html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement 11-961/S-039." We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

In addition, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant new risk information relating to your drug product. We are hereby requesting that all promotional materials for your drug product that include representations about your drug product be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important revised package labeling. Please submit a written response to this request 14 days from the date of this letter stating whether you intend to comply with this request, to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications by facsimile at (301) 796-9878 or at 5901-B Ammendale Road, Beltsville, MD 20705.

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

If you have any questions, email Renmeet Grewal, Pharm.D., Regulatory Project Manager at [Renmeet.Grewal@FDA.HHS.GOV](mailto:Renmeet.Grewal@FDA.HHS.GOV).

Sincerely,

*{See appended electronic signature page}*

Thomas Laughren, M.D.  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure (labeling)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Thomas Laughren  
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