DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Graydon A. Elliott, Director, Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

RE: NDA # 21-283
Diovan® (valsartan) Tablets
MACMIS ID # 16734

Dear Mr. Elliot:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed eight online banners (DIO-901116 – DIO-901123) (banners) for Diovan® (valsartan) Tablets submitted by Novartis Pharmaceuticals Corporation's (Novartis) under cover of Form FDA 2253. All eight banners are misleading in that they present efficacy claims for Diovan, but fail to communicate **any** risks associated with its use. Thus, the banners misbrand the drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations, see 21 U.S.C. §§ 352(a), (n); 321(n); 21 CFR 202.1(e)(3)(i), (e)(5), (e)(6)(i), and pose a potential risk to public health because they suggest that Diovan is safer than has been demonstrated.

Background

The INDICATIONS AND USAGE section of the approved product labeling (PI) for Diovan states, "Diovan® (valsartan) is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents."

Diovan is associated with a number of serious risks. The PI for Diovan includes a black box warning concerning the risk of injury or death to the developing fetus when used in pregnancy, in addition to warnings and precautions regarding the risks of hypotension and impaired renal function. Furthermore, the most common adverse reactions in hypertension clinical trials were headache and dizziness.

Omission of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. The banners present various efficacy claims for Diovan, but fail to communicate **any** risk information. For example, the banners present the following efficacy claims for Diovan:

- "Ask your doctor how Diovan can help lower your blood pressure."
- "High blood pressure is a warning sign you shouldn't ignore. . . . Save $20 on your next Diovan prescription."
- "Know the warning sign of high blood pressure. . . . Find out how to save $20 on your next Diovan prescription."
- "Clicking here won't lower your blood pressure . . . But it could lower the cost of medication
  by $20. . . . Save $20 on your next Diovan prescription."

The banners, however, entirely omit **all** risk information, including the warnings, precautions, and the most frequently reported adverse events from the PI. We note that a link to the PI and Patient Product Information (PPI) is included at the bottom of the banners. However, this does not mitigate the misleading omission of risk information from the banners. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any effectiveness or safety claims made in that part. By omitting the most serious and frequently occurring risks associated with the drug, the banners misleadingly suggest that Diovan is safer than has been demonstrated.

Conclusion and Requested Action

For the reasons discussed above, the banners misbrand Diovan in violation of the Federal Food, Drug, and Cosmetic Act and implementing regulations. See 21 U.S.C. §§ 352(a), (n); 321(n); 21 CFR 202.1(e)(3)(i), (e)(5), & (e)(6)(i).

DDMAC requests that Novartis immediately cease the dissemination of violative promotional materials for Diovan such as those described above. Please submit a written response to this letter on or before September 15, 2008, stating whether you intend to comply with this request, listing all violative promotional materials for Diovan such as those described above, and explaining your plan for discontinuing use of such materials.

Please direct your response to the undersigned at the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, 5901-B Ammendale Road, Beltsville, MD, facsimile at 301-796-9878. In all future correspondence regarding this matter, please refer to MACMIS # 16734 in addition to the NDA number. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Diovan comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Sangeeta Vaswani, Pharm.D.
Acting Group Leader
Division of Drug Marketing,
Advertising, and Communications

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

/s/

Sangeeta Vaswani
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