

**TRANSMITTED BY FACSIMILE**

Sandra A. Kerr
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
351 N. Sumneytown Pike, UG3BC-10
North Wales, PA 19454-2505

RE: NDA No. 21-995 JANUVIA™ (sitagliptin) Tablets
NDA No. 20-788 PROPECIA® (finasteride) Tablets
NDA No. 20-829, 20-830, 21-409 SINGULAIR™ (montelukast sodium) granule;
tablet, chewable; tablet, film coated
NDA No. 21-549 EMEND® (aprepitant) Capsules
MACMIS ID # 17312

Dear Ms. Kerr:

As part of its monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed Merck and Company, Incorporated's (Merck) sponsored links on internet search engines (e.g., Google.com) for the following products: JANUVIA™ (sitagliptin) (Januvia), PROPECIA® (finasteride) Tablets (Propecia), SINGULAIR™ (montelukast sodium) granule and tablets (Singulair), and EMEND® (aprepitant) Capsules (Emend). The sponsored links cited in this letter are misleading because they make representations and/or suggestions about the efficacy of Januvia, Propecia, Singulair, and Emend, but fail to communicate **any** risk information associated with the use of these drugs. In addition, the sponsored links for Januvia, Propecia, and Emend inadequately communicate the drugs' indications. Furthermore, the links for Januvia, Singulair, and Emend fail to use the required established name. Thus, the sponsored links misbrand the drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and FDA implementing regulations. See 21 U.S.C. 352(a) & (n), 321(n); 21 CFR 201.10(g)(1), 202.1(b)(1), (e)(3)(i), (ii) & (e)(6)(i).

Background***Januvia***

According to its FDA-approved product labeling (PI), Januvia is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The PI includes important limitations of use, such that Januvia should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings, and that Januvia has not been studied in combination with insulin.

Januvia is associated with a number of risks, as reflected in the Contraindications, Warnings and Precautions, and Adverse Reactions sections of its PI.

Propecia

According to its FDA-approved PI, “PROPECIA is indicated for the treatment of male pattern hair loss (androgenetic alopecia) in **MEN ONLY**. Safety and efficacy were demonstrated in men between 18 to 41 years of age with mild to moderate hair loss of the vertex and anterior mid-scalp area

Efficacy in bitemporal recession has not been established.

PROPECIA is not indicated in women . . . [or] children . . . ” (emphasis in original).

Propecia is associated with a number of risks, as reflected in the Contraindications, Warnings, Precautions, and Adverse Reactions sections of its PI.

Singulair

According to its FDA-approved PI, Singulair is indicated, among other things, for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 6 months of age and older).

Singulair is associated with a number of risks, as reflected in the Contraindications, Precautions and Adverse Reactions sections of its PI.

Emend

According to its FDA-approved PI, Emend is indicated, among other things, in combination with other antiemetic agents for the:

- prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin
- prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Emend is associated with a number of risks, as reflected in the Contraindications, Precautions, and Adverse Reactions sections of its PI.

Omission of Risk Information

Promotional materials, other than reminder pieces, which include the name of the drug product but do not include indications or other representations or suggestions relative to the drug product (see 21 CFR 200.200, 201.100(f), 202.1(e)(2)(i)), are required to disclose risk and other information about the drug. Such 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 sponsored links present the following claims:

- [Type 2 Diabetes Info](#)
Get the Facts About Type 2 Diabetes
Healthy Recipes & Management Tips
www.JANUVIA.com
- [Finasteride Treatment](#)
You May be able to keep
some of the hair that you have
www.PROPECIA.com
- [Allergy Medication](#)
Relief of Allergy Symptoms:
Learn About A Treatment Option.
www.SINGULAIR.com
- [Chemo Nausea & Vomiting](#)
www.EMEND.com Learn How It Affects You And How To Help Prevent It.

These sponsored links make representations and/or suggestions about the efficacy of Januvia, Propecia, Singulair, and Emend, respectively, but fail to communicate **any** risk information. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug.

By omitting the most serious and frequently occurring risks associated with the drugs promoted in the links above, the sponsored links misleadingly suggest that Januvia, Propecia, Singulair, and Emend are safer than has been demonstrated. We note that these sponsored links contain a link to the products' websites. However, this is insufficient to mitigate the misleading omission of risk information from these promotional materials.

Inadequate Communication of Indication

The sponsored links for Januvia, Propecia, and Emend provide very brief statements about what the drugs are for; however, these statements are incomplete and misleading, suggesting that these drugs are useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience.

Specifically, the sponsored link for Januvia misleadingly broadens the indication for Januvia by linking the drug's name to type 2 diabetes ("[Type 2 Diabetes Info](#). Get the Facts About Type 2 Diabetes . . .") without disclosing any of the important limitations reflected in the drug's PI to its use for this condition (see Background section above).

The sponsored link for Propecia misleadingly broadens the indication for Propecia by implying that all patients with hair loss are candidates for Propecia therapy ("You May be able to keep some of the hair that you have"), when this is not the case. Rather, Propecia is indicated for the treatment of male pattern hair loss in **men only** and is not indicated for women or children.

Finally, the sponsored link for Emend misleadingly broadens the indication for Emend by failing to reveal that the drug is indicated in combination with other antiemetic agents and not as monotherapy.

Failure to Use Required Established Name

The sponsored links for Januvia, Singulair and Emend fail to present the full established name of the drugs being promoted, despite the requirement to do so. See 21 CFR 201.10(g)(1) & 202.1(b)(1).

Conclusions and Requested Action

For the reasons discussed above, the sponsored links misbrand Januvia, Propecia, Singulair, and Emend, in violation of the Act and FDA regulations. See 21 U.S.C. 352(a) & (n), 321(n); 21 CFR 201.10(g)(1), 202.1(b)(1), (e)(3)(i), (ii) & (e)(6)(i).

DDMAC requests that Merck immediately cease the dissemination of violative promotional materials for Januvia, Propecia, Singulair, and Emend, such as those described above. Please submit a written response to this letter on or before April 9, 2009, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) in use for these drugs as of the date of this letter, identifying which of these materials contain violations such as those described above, and explaining your plan for discontinuing use of such materials. Finally, we encourage you to review your promotional materials for the other prescription drug products that Merck promotes in the United States and to discontinue or revise any materials with the same or similar violations, and request that your response address this issue as well.

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 301-847-8444. In all future correspondence regarding this matter, please refer to MACMIS # 17312 in addition to the NDA numbers. 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 Januvia, Propecia, Singulair, and Emend comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Shefali Doshi, M.D.
Regulatory Review Officer
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/

Shefali Doshi
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