DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Tacy Pack
Senior Associate Director, Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Re: NDA # 21-395
Spiriva® Handihaler® (tiotropium bromide inhalation powder)
MACMIS # 14059

Dear Ms. Pack:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a promotional piece (SV-11305) for Spiriva® Handihaler® (tiotropium bromide inhalation powder) (Spiriva) submitted by Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) under cover of Form FDA 2253. This four-page promotional piece is misleading because it fails to reveal materials facts. The promotional piece therefore misbrands the drug in violation of the Federal Food, Drug and Cosmetic Act (Act) and FDA implementing regulations. See 21 U.S.C.§§352(a) & 321(n).

Omission of Material Facts

The first page of the promotional piece contains the header, "**ATTENTION: ATROVENT® (IPRATROPIUM BROMIDE) INHALATION AEROSOL (CFC FORMULATION) MDI IS BEING DISCONTINUED**." The next line reads, "**Now is the time to Consider stepping up to the sustained efficacy of SPIRIVA[1,2]**" (original emphasis). The last page of the promotional piece contains the header**,** "SPIRIVA: Same copay tier as Atrovent® (ipratropium bromide) Inhalation Aerosol with most major insurers."

Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made. This presentation is misleading because it fails to reveal that Atrovent remains commercially available in a hydrofluoroalkane-134a (HFA) formulation (Atrovent® HFA Inhalation Aerosol).

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[1] Data on File, Boehringer Ingelheim Pharmaceuticals, Inc.

[2] Vincken W, van Noord JA, Greefhorst APM, et al. Improved health outcomes in patients with COPD during 1 yr's treatment with tiotropium. *Eur Respir J*. 2002;19:209-216.

Conclusion and Requested Action

The promotional piece is misleading because it fails to reveal material facts. Therefore, it misbrands the drug in violation of the Act and FDA implementing regulations. See 21 U.S.C.§§352(a) & 321(n).

DDMAC requests that Boehringer immediately cease the dissemination of promotional materials for Spiriva the same as or similar to those described above. Please submit a written response to this letter on or before June 9, 2006, describing your intent to comply with this request, listing all promotional materials for Spiriva that contain claims that are the same as or similar to those described above, and explaining your plan for discontinuing use of these materials. Please direct your response to me 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 20705-1266, or by facsimile at 301-796-9877. In all future correspondence regarding this matter, please refer to MACMIS ID # 14059 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 Spiriva comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Michelle Safarik, MSPAS, PA-C
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/

Michelle Safarik

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