



TRANSMITTED VIA FACSIMILE

Thomas M. Casola
Executive Director
Office of Medical/Legal
U.S. Human Health
Merck & Co., Inc.
P.O. Box 1000, UG3BC-10
North Wales, PA 19454-1099

**RE: NDA #21-227
Candidas (caspofungin acetate)
MACMIS ID # 10161**

Dear Mr. Casola:

The Division of Drug Marketing, Advertising, and Communications' (DDMAC) has identified a Merck sales representative promoting Candidas (caspofungin acetate) for an unapproved use in the commercial exhibit hall of the American Society of Clinical Oncology (ASCO) Annual Meeting in May 2001. In addition, DDMAC has identified a violative convention panel for Candidas that appeared in the commercial exhibit hall of the American Society of Health System Pharmacists' (ASHP) Annual Meeting in June 2001. We find the sales representative's activities and the convention panel in violation of the Federal Food, Drug, and Cosmetic Act and its applicable regulations for the following reasons.

Promotion of Unapproved Use

At the ASCO Annual Meeting in May 2001, a Merck sales representative asked a visitor, "would you like to have off-label information sent to you about Candidas?" The representative then swiped the visitor's name badge in order to have the "off-label information" sent by mail. The visitor then received mailed information about Candidas that included information about the unapproved use for candida. The information came with a cover letter, which stated "this is in response to your request for information which you submitted at a recent medical meeting regarding Candidas (caspofungin acetate). Your inquiry concerned medical and product information for Candidas pertaining to your formulary request." Thus, the representative's question and activities show that Merck intended for Candidas to be used for an unapproved use. Candidas is indicated for the treatment of invasive aspergillosis in patients who are refractory or intolerant to other therapies (i.e. amphotericin B, lipid formulations of amphotericin B, and/or itraconazole) and Merck has not demonstrated that Candidas is safe or effective for any other uses at this time.

Misleading Indication and Lack of Fair Balance

The single convention panel for Cancidas that was used at the ASHP Annual Meeting included part of the indication for Cancidas (invasive aspergillosis), a statement of efficacy versus fungus, a class designation as anti-fungal echinocandin, and a website address, www.cancidas.com. However, the convention panel failed to provide the complete indication and failed to include important risk information for Cancidas including the warnings, precautions, and major side effects. Thus, the panel is misleading because it lacks the appropriate indication and lacks fair balance.

Requested Action

We request that the Merck sales representative immediately cease promoting Cancidas for unapproved uses and cease disseminating information on unapproved uses for Cancidas. We also request that Merck stop using the violative Cancidas panel and all other promotional materials that contain the same or similar presentations. In addition, we request that you submit a written response by July 12, 2001 describing your intent and plans to comply with the above. The response should include a list of the materials discontinued and the date they were discontinued.

You should direct your response to the undersigned by facsimile at (301) 594-6771, or in writing to the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 10161 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

James R. Rogers, Pharm.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/

James Rogers

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