

MAR 14 1997

TRANSMITTED VIA FACSIMILE

Ellen R. Westrick
Senior Director
Office of Medical/Legal
Merck & Co., Inc.
Sumneytown Pike
West Point, PA 19486

RE: NDA# 19-558
Prinivil (lisinopril) Tablets
MACMIS ID # 5235

Dear Ms Westrick:

The Division of Drug Marketing, Advertising and Communications (DDMAC), as part of its routine surveillance program, has reviewed a journal advertisement and brochure promoting Prinivil (lisinopril) tablets that was disseminated by or on behalf of Merck & Co., Inc., (Merck). These materials describe Cal Ripken, Jr., as being "The Hardest Working Man in Baseball," and contain concurrent references to Mr. Ripken and Prinivil.

DDMAC has reviewed these promotional pieces and concluded that they are in violation of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder. Our specific objections to the journal ad and brochure are discussed below and should apply to all applicable promotional materials for Prinivil.

These promotional materials are false and/or misleading because of the presentation of Cal Ripken, Jr. in association with Prinivil. Specifically, the claim "Both On the Job. Everyday" is a misrepresentation in the context in which it is presented. In these promotional materials, it appears that Mr. Ripken is endorsing Prinivil. However, Mr. Ripken does not take Prinivil and does not have hypertension. The disclaimer that Mr. Ripken is not hypertensive and does not take Prinivil lacks significant prominence and does not balance or clarify the misrepresentation of the product endorsement that is suggested or stated throughout these materials.

Merck should immediately discontinue use of this and other promotional materials that are similarly violative. Please respond in writing by March 28, 1997, with your intent to comply with the above. Address your response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Merck that only

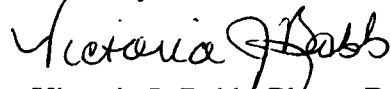
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written communications are considered official.

In all future correspondence regarding the issues raised in this letter, please refer to MACMIS ID # 5235 in addition to the NDA number.

Sincerely,

A handwritten signature in black ink that reads "Victoria J. Babb". The signature is written in a cursive style with a large, stylized initial "V".

Victoria J. Babb, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

Ellen Westrick
Merck & Co., Inc.
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File Name: Prinivil/nov.1

Drafted: Babb	Date: March 4, 1997
Comment: Drezin	March 6, 1997
Revised: Babb	March 13, 1997
Concur w/Comments:Drezin	March 13, 1997
Revised: Babb	March 14, 1997

CC:
HFD-240/NDA # 19-558
HFD-240/Count/Chron/Babb(2)/Abrams
HFD-110/Bongiovanni/Chen
HFD-110/NDA # 19-558

MACMIS ID # 5235

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253 ID#: 48874 Material ID#(s): DAPRV4

Due Date:
Close Out: N

NOV Status: RELEASABLE