DEPARTMENT OF HEALTH & HUMAN SERVICES

FOI

Food and Drug Administration
Rockville MD 20857

NOV 23 1998

TRANSMITTED VIA FACSIMILE

James A. Parker, Jr.
Director
Advertising and Labeling
Worldwide Regulatory Affairs
Parke-Davis
201 Tabor Road
Morris Plains, NJ 07950

Re: **NDA 20-702**
Lipitor (atorvastatin calcium) Tablets
MACMIS ID #7301

Dear Mr. Parker:

This letter is in reference to Parke-Davis's (Parke-Davis) submission of promotional material under cover of Form FDA 2253 for Lipitor (atorvastatin calcium). This material consists of a 60 second direct-to-consumer (DTC) television broadcast advertisement ("Rainstorm"/LHJ:60, Commercial). The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards the television broadcast advertisement to be false or misleading under the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. A description of the objections is provided below. DDMAC references a November 21, 1998 teleconference between Parke-Davis and DDMAC during which DDMAC requested that the airing of the television advertisement be immediately discontinued.

The television broadcast advertisement fails to sufficiently reveal material facts with respect to the effects, or lack thereof, of the product in light of the efficacy representations made regarding the product's use for lipid-lowering. The communication of important information related to the product's use for lipid-lowering is inadequate.

Lipitor is indicated as an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels in patients with primary hypercholesterolemia and mixed dyslipidemia. However, unlike several other HMG-CoA reductase inhibitors currently on the market, Lipitor is not indicated for reduction in cardiovascular morbidity and mortality. The fact that the relationship between lipid lowering and cardiovascular morbidity and mortality has not been proven for Lipitor is important information that would play into a consumer's decision process when deciding whether to

discuss this product with his or her health care provider and when considering treatment with Lipitor.

The lipid-lowering use of Lipitor and indeed the magnitude of the reductions seen following treatment with Lipitor have been made the focus of this television advertisement. This focus on the magnitude of change coupled with the visual images as the advertisement progresses from beginning to end work together to strongly persuade consumers to consider Lipitor as a treatment option that is likely to have long-term benefits on disease and survival. And, although Parke-Davis has included a super in the advertisement which states that, "The effect of Lipitor on cardiovascular morbidity and mortality has not been determined", this super is not effective for the purpose of balancing or correcting the overall impression given by the advertisement of the known and unknown clinical effects of Lipitor. This language is technical, not in consumer-friendly language and, therefore, not likely to communicate to consumers that the relationship between Lipitor's lipid-lowering effect and its effect on cardiovascular disease or survival is not known. DDMAC previously suggested that Parke-Davis use language appropriate to a consumer audience in DTC pieces in a letter dated, April 17, 1998, providing comments to Parke-Davis on other proposed consumer advertising materials.

Parke-Davis should immediately discontinue the use of the television broadcast advertisement and other promotional materials that contain the same or similar representations for Lipitor discussed above. Parke-Davis should submit a written response to DDMAC on or before December 3, 1998, confirming that Parke-Davis has discontinued the use of such materials, and the date of discontinuation. Please address your response to the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #7301 in addition to the NDA number. DDMAC reminds Parke-Davis that only written communications are considered official.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications