## DEPARTMENT OF HEALTH & HUMAN SERVICES



Public Health Service

Food and Drug Administration Rockville MD 20857

## FILE COPY

August 27, 2001

Chris Fischer Public Citizen 1600 20th Street NW Washington, DC 20009

Dear Mr. Fischer:

Your petition requesting the Food and Drug Administration to add a black box warning and additional consistent bolded warnings about the labeling of all HMG-CoA Reductase Inhibitors marketed in the United States, was received by this office on 08/27/01. It was assigned docket number 01P-0372/CP 1 and it was filed on 08/27/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

P Butter MM

Dockets Management Branch

01P-031%

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