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**APPLICATION NUMBER: 20-702/S025**

**APPROVAL LETTER**



**Application #(s):** NDA 20-702/S-025

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**Document Group:** Approval Letters  
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**COMIS Decision:** AP: APPROVAL

**Drafted by:** Mas/May 30, 2001  
**Revised by:**  
**Initialed by:** M. Parks 6.4.01/E. Herman 6.5.01/X. Ysern 6.4.01/S. Moore 6.5.01/K. Davis-Bruno 6.5.01/T. Sahlroot & for S. Wang 6.4.01/E. Galliers 6.4.01  
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**DFS Key Words:**

**Notes:** Geriatric Labeling

**Linking Instructions:** If this is the first action on the application, link the outgoing letter to the initial submission, RS, AR, or FO coded incoming document for the supplement being acted on, as appropriate. Otherwise, the outgoing letter must be linked to the major amendment submitted in response to the previous action letter. In addition, the outgoing document should also be linked to all associated amendments and correspondences included in the action.



**APPEARS THIS WAY  
ON ORIGINAL**



NDA 20-702/S-025

Pfizer Ireland Pharmaceuticals  
Attention: Paul GH Nitschmann, M.D.  
Director, Worldwide Regulatory Strategy  
235 East 42nd Street  
150/7/12  
New York, NY 10017

Dear Dr. Nitschmann:

Please refer to your supplemental new drug application dated August 10, 2000, received August 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) tablets.

We acknowledge receipt of your submissions dated October 20 and 23, and November 17, 2000, and January 25, March 5 and 26, and May 25 and 30, and June 6, 2001.

This supplemental new drug application provides for changes to the "CLINICAL PHARMACOLOGY, Special Populations, Geriatric" subsection regarding age-related differences in LDL-lowering and for the modification of the "PRECAUTIONS, Geriatric Use" subsection of the Lipitor package insert. Specifically, efficacy and safety results in the elderly versus non-elderly patients studied in the ACCESS trial have been added to the "Geriatric Use" subsection.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted June 6, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-702/S-025." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We note that a Written Request (WR) for pediatric studies in patients with heterozygous familial hypercholesterolemia (heFH) was sent to you on February 16, 1999, and amendments on September 6, 1999, and June 8, 2000. No specific studies in Frederickson Type IIa and IIb are required. We hereby waive the requirement for pediatric studies in these groups, and we defer submission of the pediatric studies in heFH until March 31, 2002.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.

Director

Division of Metabolic and Endocrine Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

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/s/

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David Orloff  
6/8/01 11:51:01 AM

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