

Zydus Pharmaceuticals (USA) Inc.

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June 16, 2006

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23 (HFA-305)
12420 Parklawn Drive
Rockville, MD 20857

Re: Citizen's Petition to FDA Seeking Immediate Approval of ANDA No. 77-837 upon
June 23, 2006 Patent Expiration Of U.S. Patent No. 4,444,784

CITIZEN'S PETITION

The undersigned submits this Petition under the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301 *et seq.*, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 C.F.R., Part 5.10) to request that the Commissioner of Food and Drugs take administrative action to immediately approve ANDA No. 77-837 upon the June 23, 2006 patent expiration of U.S. Patent No. 4,444,784.

A. ACTION REQUESTED

This Petition is respectfully submitted to request that the FDA immediately provide tentative approval of ANDA No. 77-837 and provide full approval of such ANDA upon the June 23, 2006 patent expiration of U.S. Patent No. 4,444,784.

B. STATEMENTS OF GROUNDS

Petitioner, Zydus Pharmaceuticals USA, Inc., ("Zydus"), a Delaware Corporation, produces and sells generic drugs by its approved ANDAs. Zydus has its corporate headquarters located in Princeton, New Jersey. By this Petition, Zydus respectfully submits that its ANDA 77-837 directed to simvastatin tablets (5, 10, 20, 40 and 80 mg tablets) should be approved by the June 23, 2006 expiration of U.S. Patent No. 4,444,784.

2006P-0258

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On May 25, 2006, the FDA filed an Appeal to the United States Court of Appeals for the District of Columbia in respect of the Decision of the U.S. District Court for the District of Columbia in Ranbaxy Laboratories Limited v. Leavitt, Civ. Action No. 05-CV-1838 (RWR). In the Appeal, the FDA maintains that the successor-in-interest to the first ANDA filer for the drug simvastatin (Zocor[®]) is not entitled to 180 days of generic marketing exclusivity. Zydus respectfully concurs in the FDA's position. Zydus understands the FDA is seeking expedited review of its Appeal, and that the successor-in-interest to the first ANDA filer has agreed to such schedule.

Zydus asserts that its ANDA No. 77-837 is complete and, thus, should be approved upon the expiration of the only Patent for which a Paragraph III Certification remains in force, that is, United States Patent No. 4,444,784. As the FDA's position is that the successor-in-interest to the first ANDA filer is not entitled to any period of generic marketing exclusivity, Zydus asserts that all ANDA filers in position for final approval of their ANDAs should be approved subsequent to the expiration of the last Orange Book-listed Patent for which a Paragraph III Certification was made. Zydus respectfully submits that the FDA cannot delay final approval, given its position in the Appeal.

Zydus also asserts that the public would benefit by the approval of Zydus ANDA during the pendency of the Appeal. Prices for generic and "authorized generic" products could be significantly inflated due to less competition in the marketplace.

Zydus, therefore, respectfully requests that the FDA expeditiously approve ANDA 77-837 upon the June 23, 2006 expiration of U.S. Patent No. 4,444,784.

C. ENVIRONMENTAL IMPACT

The action requested by this Petition qualifies for a categorical exclusion under 21 C.F.R. § 25.31(a). Therefore, we submit, an environmental assessment is not required.

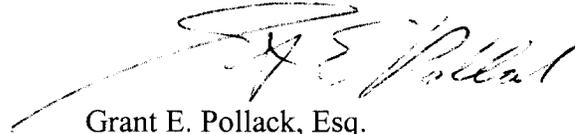
D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30(b), information on the economic impact of the action requested by this Petition will be submitted if requested by the Commissioner.

E. CERTIFICATION

The undersigned certifies that, to the best of their knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "G.E. Pollack", written over a horizontal line.

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Dated: June 16, 2006