AUROBINDO PHARMA LTD.

April 4, 2007

5868

Food Drug Administration
Office of Generic Drugs, HFD-600
7519 Standish Place
Rockville MD 20855

APR -5 P12:38

Kind Attention: Mr. Gary J Buehler, Director

SUB: AMLODIPINE BESYLATE - COMMENTS ON FDA LETTER

Dear Sir,

This refers to your letter of March 28, 2007 with respect to our Amlodipine besylate ANDA (No. 78-021). We have provided herewith our comments on the questions forwarded by you.

Q1. What date controls FDA's giving effect to the decision in Pfizer Inc. v. Apotex, Inc., No.2006-1261 (Fed.Cir. March 22, 2007) ("Apotex decision") holding that Pfizer's patent 4,879,303 ("the '303 patent") is invalid? Can FDA treat the '303 patent as invalid as of March 22, 2007, or must FDA await the issuance of the mandate? Is the answer the same for all purposes, that is, for determining the applicability of pediatric exclusivity, the triggering of 180-day exclusivity, and the eligibility of other ANDA applicants for final approval?

A. FDA may not wait for the issuance of mandate and can treat the US 4,879,303 patent invalid as of March 22, 2007 based on the Court Of Appeals decision for the purpose of determining the triggering event of 180-day exclusivity for the first ANDA application with Paragraph IV certification (505 (j)(5)(b)(iv) and Guidance of March 2000). In accordance with Section 505 (j)(2)(A)(vii)(IV) of FDCA, once exclusivity has been triggered, the FDA may not approve additional ANDAs for 180 days.

Q2. If FDA must await the issuance of the mandate, does pediatric exclusivity bar approval of all unapproved ANDAs in the meantime?

A. Yes, if FDA awaits the issuance of the mandate, pediatric exclusivity attached to US '303 should bar the approval of all unapproved ANDAs.

C 6

Regd. Off. : Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500 038, INDIA. Phone : ++91-40-66725000, Fax :++91-40-23746833, 23741080
U.S.A. Off. : 2400 Route 130 North Dayton, NJ 08810, Phone : 732-839-9406, 732-839-9400, Fax : 732-355-9940
E-mail : info@aurobindo.com, Web Site : www.aurobindo.com

2007N-0123

Q3. If and when the Apotex decision is implemented, what is the effect of the decision that the '303 patent is invalid on the obligation of an ANDA applicant to change its certification? Must Pfizer delist its patent, so that certifications can be withdrawn? Or can FDA treat an invalid patent as delisted as a matter of law, and presume the withdrawal of the certifications? Or must the ANDA applicants file paragraph II certifications stating that the '303 patent has expired?

A. Once the Apotex decision is implemented, FDA should treat an invalid patent as delisted as a matter of law. In view of this, all pending Para III / Para IV certifications will be nullified after the exhaustion of first filers 180-day exclusivity.

Q4. If and when the Apotex decision is implemented and the patent is treated as invalid, does pediatric exclusivity attach to the '303 patent with respect to any unapproved ANDAs? Does it matter whether the ANDA applicant filed a paragraph III or IV certification before patent expiration?

A. No, the pediatric exclusivity does not attach to an invalid patent. It will not matter, whether the ANDA applicant filed Para III / Para IV certification before the patent expiration.

Q5. Does 180-day exclusivity triggered before a patent expires continue to bar approvals of other ANDAs after the patent expires, even if other ANDA applicants change their certifications to paragraph II or withdraw their certifications altogether?

A. Yes, the 180-day exclusivity triggered before the patent expiry, should bar approval of all other ANDAs until the 180-day exclusivity exhausted.

Sincerely yours,

Prasada Kambham
US Agent for Aurobindo Pharma Limited

Regd. Off. : Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500 038. INDIA. Phone : ++91-40-66725000, Fax : ++91-40-23746833, 23741080
U.S.A. Off. : 2400 Route 130 North, Dayton, NJ 08810, Phone : 732-839-9406, 732-839-9400, Fax : 732-355-9940
E-mail : info@aurobindo.com, Web Site : www.aurobindo.com