DEPARTMENT OF HEALTH & HUMAN SERVICES MAR 29 P4:18

Food and Drug Administration
Rockville, MD 20857

Dear

This letter is in reference to your pending ANDA for amlodipine besylate tablets. As you may be aware, on March 26, 2007, Mylan Laboratories, Inc. filed a complaint against the Food and Drug Administration ("FDA") seeking to enjoin FDA from immediately approving abbreviated new drug applications for amlodipine besylate products. *Mylan Laboratories, Inc. v. Michael Leavitt*, CA No. 07-579 (RMU) (D.D.C.). Because the recent developments in the amlodipine besylate patent litigation (in particular, the Federal Circuit's March 22, 2007 decision in *Pfizer Inc. v Apotex, Inc.*, No. 2006-1261 (Fed. Cir. March 22, 2007)) presented several regulatory issues that need to be resolved before any applications could be approved, FDA informed the court (in CA No. 07-579) that it planned to solicit comments from interested parties before it reached decisions on the matters that Mylan sought to enjoin. The court has memorialized FDA's proposal, and enjoined the agency from implementing its decisions once made, until 5:00 pm on April 13, 2007, to allow the court the opportunity to review the FDA decisions. *Mylan Laboratories*, CA No. 07-579, Order (March 26, 2007).

The FDA is considering the following questions. Should you wish to comment on them, your response will be posted at http://www.fda.gov/cder/ogd/index.htm. Other submissions relevant to these issues will also be posted at this address. Please send your response, if any, by close of business on April 4, 2007 to:

Food and Drug Administration
Office of Generic Drugs, HFD-600
Attention: Gary J. Buehler, Director
7519 Standish Place
Rockville, MD 20855

1. 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?

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

3. 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?

4. 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?

5. 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?

We note that several citizen petitions have been submitted that also raise issues relevant to approval of ANDAs for products containing amlodipine. The petition docket numbers are: 2007P-0116, submitted by Mylan Pharmaceuticals, Inc; 2007P-0110 and 2007P-0111 submitted by Pfizer Inc. If you believe your comments are also relevant to consideration of those petitions, you may submit your comments to the petitions dockets as well. In addition, FDA may consider relevant comments received in this context when answering the petitions.

Thank you for your consideration of these questions. If you have any questions regarding this letter, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 240-276-9310.

Sincerely,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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/s/

Gary Buehler
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