DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

rec'd 10/29/07

SENT VIA TELEFAX

Reference Number: OGD #07-1254

Dear ANDA Applicant:

We are writing to solicit comment on certain legal/regulatory issues that pertain to generic drug applications for Acarbose Tablets. This letter is being sent to all applicants with pending abbreviated new drug applications (ANDAs) for Acarbose Tablets, and is being posted on FDA's web-site at http://www.fda.gov/cder/ogd/index.htm#New.

The reference listed drug (RLD) for Acarbose Tablets is Precose Tablets, the new drug application (NDA) held by Bayer Pharmaceuticals (Bayer). There is one patent listed for Acarbose Tablets, U.S. Patent No. 4,904,769 (the '769 patent), which expires on September 6, 2009. As you probably are aware, for it appears on the "Paragraph IV list" on FDA's website, at least one ANDA for Acarbose Tablets containing a paragraph IV certification was received by the agency on March 22, 2005. By virtue of this filing, at least one applicant became eligible for 180-day generic drug exclusivity.

As you know, the agency makes determinations regarding 180-day exclusivity only when it is in the position to either approve an application that may be eligible for 180-day exclusivity, or to act on a subsequent applicant's ANDA as to which final approval may be delayed by another application's eligibility for exclusivity.

As of the date of this letter, which is more than 30 months from March 22, 2005, no first applicant's ANDA has been approved. Also, on April 16, 2007, Bayer requested that the '769 patent be "delisted" as to Precose, i.e., they withdrew the patent information. On September 26, 2007, FDA indicated in its "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book), available on FDA's website at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020482&Product_No=001&table1=OB_Rx, that the request to delist this patent had been submitted on April 16, 2007.

To determine whether any ANDA referencing Precose is eligible for final approval, the agency must consider how the 180-day generic drug exclusivity forfeiture provisions at section 505(j)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) apply to this set of facts. As part of the process for making such a determination, we are seeking your views regarding the applicability of sections 505(j)(5)(D)(i)(IV) -- failure to obtain tentative approval within 30 months -- and 505(j)(5)(D)(i)(I)(aa)(BB) -- failure to market by 30 months. We also are interested in your views regarding the applicability of section 505(j)(5)(D)(i)(I)(bb)(CC) -- relating to the delisting of a patent.

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We are asking that you submit your comments to us by close of business on Wednesday, October 10, 2007. Please include the OGD Reference Number listed above in your correspondence.

If you have any questions regarding this correspondence, please contact Cecelia M. 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
9/26/2007 10:39:25 AM
for Gary Buehler