Boehringer Ingelheim
Roxane Laboratories

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

rec'd 11/6/07

September 28, 2007

Elizabeth A. Ernst
Director
DRA-Multisource Products

Telephone (614) 272-4785
Telefax (614) 276-2470
E-Mail
ernst.ea@boehringer-ingelheim.com

1809 Wilson Road
Columbus, OH 43228

Reference Number: OGD #07-1254

Acarbose Tablets
Response to Request for Comments
Controlled Correspondence

Roxane Laboratories, Inc. (Roxane) responds to the agency's solicitation for comments on pending abbreviated new drug applications (ANDAs) for Acarbose Tablets (OGD #07-1254). In its September 26, 2007 fax correspondence, the agency specifically inquires about Roxane's opinion on how the Federal Food, Drug and Cosmetic Act's (the Act) 180 day generic drug exclusivity forfeiture provisions, as well as the patent delisting provision, apply to these specific set of facts. As detailed below, Roxane believes that any otherwise approvable ANDA for acarbose tablets containing a Paragraph IV certification that U.S. Patent No. 4,904,769 (the '769 Patent) which expires September 6, 2009, is invalid, not infringed and unenforceable should be granted immediate final approval.

Roxane believes that at least one, if not two, forfeiture events pursuant to the FDA Act as modified by the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 (Public Law 108-173) have occurred, mandating the loss of the 180-day exclusivity for the first applicant and allowing for the final approval of any other applicant's otherwise approvable ANDA.

The MMA was signed into law on December 8, 2003. Any ANDA filed on or after December 8, 2003 is subject to the regulations contained within this statute. Per the Paragraph IV Certification List on the fda.gov/cder/ogd website, the first ANDA for acarbose tablets that contained a Paragraph IV certification was filed on March 22, 2005. This filing is therefore subject to the regulations contained within the MMA.

MMA Section 1102(D) details the various circumstances under which the forfeiture of 180-day exclusivity could be triggered. Pursuant to MMA Section 1102(D)(i)(IV) thereof (FDA Act §505(j)(5)(D)(i)(IV)), this first applicant forfeits its 180 days of market exclusivity as the first Paragraph IV filer if it "fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed."

Because the first ANDA for acarbose tablets was filed on March 22, 2005, approval must have been obtained by September 22, 2007 (i.e. 30 months from date of filing) to avoid forfeiture. By failing to obtain approval before September 22, 2007, Roxane respectfully submits that the first applicant has forfeited its 180

2007N-0417

C 1

days of market exclusivity. As a result, any otherwise approvable Paragraph IV certification containing ANDA should receive final approval.

Alternatively, Roxane contends that if the Patent '769 is delisted from the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), a second forfeiture event has occurred. The FDA Act further outlines forfeiture of the 180-day exclusivity by a Failure to Market (§505 (j)(5)(D)(i)(I)). A forfeiture event is triggered if the first applicant fails to market the drug by the **later of** (a) 30 months after the date of submission of the application of the first applicant (§505 (j)(5)(D)(i)(I)(aa)(BB)) or (b) 75 days after the patent information submitted is withdrawn by the (NDA) holder (§505 (j)(5)(D)(i)(I)(bb)(CC).

Roxane contends that if we apply the "failure to market" provisions of the MMA to the facts at hand, the first applicant has again forfeited its 180 day exclusivity. Since the first ANDA for acarbose tablets was filed on March 22, 2005 and Bayer Pharmaceuticals, the NDA holder for Precose® Tablets (RLD for Acarbose Tablets), requested delisting of the '769 Patent (the only Orange Book listed patent) on April 16, 2007, the first applicant must have marketed by the later of: September 22, 2007 (30 months after submission of the first applicant's ANDA, as noted above) or June 30, 2007 (75 days after April 16, 2007, when Bayer withdrew the '769 Patent information). By failing to market by September 22, 2007 (the later of the two dates), Roxane respectfully submits that the first applicant has forfeited its 180 days of market exclusivity. Again as a result, any otherwise approvable ANDA should be awarded final approval.

Correspondence concerning this letter should be directed to Elizabeth Ernst, Director, DRA-Multisource Products, Roxane Laboratories, Inc.
I can be reached at (614) 272-4785 and by telefax at (614) 276-2470. In my absence, please contact Marilynn Davis, Regulatory Affairs Manager at (614) 241-4123.

Respectfully,

Elizabeth Ernst
Director, DRA-Multisource Products
Roxane Laboratories, Inc.
614-272-4785 work
614-204-0591 cell