IMPAX
LABORATORIES, INC.

2007 OCT 11

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October 10, 2007

Division of Dockets Management
Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD 20852

Via Federal Express

Re: OGD #07-1254 – Acarbose Forfeiture Issue

Dear Sir or Madam:

Impax Laboratories, Inc. ("Impax") responds to the letter from the Food and Drug Administration ("FDA") dated September 26, 2007 in which the Agency has solicited comments from companies with pending Abbreviated New Drug Applications ("ANDAs") for acarbose tablets.

Specifically, FDA seeks comments to assist the Agency in assessing the applicability of the 180-day generic drug exclusivity forfeiture provisions at section 505(j)(5)D) of the Federal Food, Drug, and Cosmetic Act to the particular set of facts as described by FDA in its September 26th letter. The issues on which FDA has specifically sought comment include the applicability of the forfeiture provisions concerning (1) the first filer's failure to obtain tentative approval within 30 months; (2) failure to market the drug within 30 months; and (3) the withdrawal of patent information by the first filer.

The questions raised by FDA are numerous and complex. Impax appreciates the opportunity to provide comments to FDA on these important issues, and intends to do so. However, due to the number of issues raised, the complexity of the relevant statutory provisions, and the lack of FDA implementation regulations or guidance on those provisions, Impax will need additional time to prepare a substantive response.

Thus, Impax wishes to notify FDA that it will submit its comments to FDA no later than close of business on October 26.

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Should FDA deem this proposed date unacceptable, we would respectfully request that FDA notify us immediately so that we can discuss this further.

Impax appreciates the opportunity to provide comments to FDA on these important issues, and looks forward to working with FDA to resolve them.

Very truly yours,
Impax Laboratories, Inc.

Mark C. Shaw
Vice-President, Regulatory Affairs
and Compliance

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