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VIA HAND DELIVERY

Douglas Throckmorton  
Acting Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research  
Food and Drug Administration  
HFD-110  
1451 Rockville Pike  
Rockville, MD 20852

Re: NDA No. 21-435; Amended Certification Regarding U.S. Patent 4,572,909

Dear Mr. Throckmorton:

This letter is to confirm that, based upon informal advice from personnel from the Office of the chief Counsel, Dr. Reddy's Laboratories, Inc., ("Reddy") is amending its patent certification regarding U.S. Patent 4,572,909 (the '909 Patent") from a paragraph III certification to a paragraph IV certification.

The '909 patent claims various salts of amlodipine, including amlodipine maleate, which is the active ingredient in Reddy's NDA. Pfizer, Inc., apparently listed the '909 patent under the theory that the patent claims amlodipine besylate, the active ingredient in Norvasc®. On December 6, 1993, Pfizer obtained a patent term extension based on the review of the Norvasc® NDA.

This extension does not cover any patent rights in associated with amlodipine maleate. Under 35 U.S.C. 156(b), the patent term extension is limited to those rights in the patent covering the active ingredient of the product in the NDA, or any salt or ester of that active ingredient.<sup>1</sup> See *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1997)

<sup>1</sup> The statute provides in relevant part as follows:

Except as provided in paragraphs(d)(5)(F), the rights derived from any patent term of which is extended under this section shall during the period during which the term of the patent is extended - (1) in the case of a patent which claims a product be limited to any use approved for the product . . . .

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(patent term extension limited to patent rights claiming "product" in NDA) and *Glaxo Operations U.K. Ltd. v. Quigg*, 894 F.2d 392, 398 (Fed. Cir. 1990) ("product" in NDA is active ingredient or any salt or ester of active ingredient).

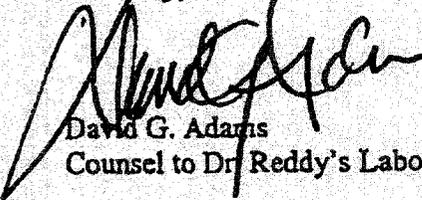
Thus, the patent term extension for the '909 patent extended only those patent rights related to amlodipine besylate and any salt or ester of amlodipine besylate. Amlodipine maleate, the active ingredient in Reddy's NDA, is not a salt or ester of amlodipine besylate. Therefore, patent rights covering amlodipine maleate expire on the original expiration date of February 25, 2003.

Reddy initially concluded that the appropriate patent certification for patent rights expiring on February 25, 2003, is a paragraph III certification. Reddy does not intend to market its product until that date and does not seek FDA approval prior to that date.

Personnel from the Office of the Chief Counsel, as well as other knowledgeable FDA personnel, have informed Reddy in informal conversations that they believe that a paragraph III certification is inappropriate and that Reddy should file a paragraph IV certification regarding all rights in the '909 patent, including those rights that will expire on February 25, 2003. These personnel expressed the view that that the extended expiration date submitted by Pfizer applies on its face to all patent rights under the '909 patent, including rights that will expire on February 25, 2003. They therefore concluded that a paragraph IV certification is appropriate regarding all patent rights based on Reddy's stipulation that it does not seek approval and will not market until February 25, 2003.

Based on this informal advice, Reddy is filing a paragraph IV certification. Reddy does not seek approval of its NDA until February 25, 2003. After that date, the only products claimed in the patent will be products containing amlodipine besylate, or containing any salt or ester of amlodipine besylate, as an active ingredient. Reddy will not infringe because it has not submitted its NDA to obtain approval of a product that contains any such active ingredient prior to the expiration of the patent.

Sincerely,



David G. Adams

Counsel to Dr. Reddy's Laboratories, Inc.

cc: Elizabeth Dickinson, Office of the Chief Counsel

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35 U.S.C. 156(b). The statute defines "product" as, *inter alia*, "drug product," 35 U.S.C. 156(f)(1)(A), which is in turn defined in relevant part as "the active ingredient . . . including any salt or ester of the active ingredient," 35 U.S.C. 156(f)(2).