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VIA HAND DELIVERY

August 21, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
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Re: Docket ID FDA - 2013-P-0862/CP1

To Whom It May Concern,

The undersigned submitted a Citizen Petition on July 12, 2013, in the above-referenced proceeding on behalf of Spec Pharma, LLC ("Petitioner") requesting that the Commissioner of Food and Drugs take certain steps regarding the pending New Animal Drug Application for BetaVet ("BetaVet NADA") submitted in 2012 by Luitpold Pharmaceuticals, Inc. ("Applicant") or one of its affiliated companies. This letter supplements and updates the above-referenced Citizen Petition.

When the Citizen Petition was submitted, Petitioner and Applicant were involved in an arbitration proceeding that had been convened to resolve, *inter alia*, certain disagreements between the parties involving their respective rights and obligations to each other stemming from their joint venture and the Development and Commercialization Agreement memorializing the same. One of the issues raised in the original arbitration was determining the parties' rights, obligations, and interests in the Beta Beta product for which an Abbreviated New Drug Application ("ANDA") was approved in July 2009. On July 12, 2013, Petitioner submitted an Amended Complaint to the existing arbitration panel adding an additional claim related to the BetaVet NADA. However, it soon became clear to Petitioner that the existing arbitration panel was not disposed to alter the hearing or pre-hearing schedules (which had been set to address only the Beta Beta issues) to accommodate the additional time necessary for Petitioner to effectively prepare the BetaVet issues. In addition, Petitioner concluded that a new arbitration panel with individuals who have more expertise in regulatory and intellectual property matters could more effectively and efficiently resolve the BetaVet dispute. On August 5, 2013, the existing arbitration panel consented to the withdrawal of Petitioner's Amended Complaint (which was acceptable to both Petitioner and Applicant) related to the BetaVet issues.

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Today, Petitioner is submitting a new Arbitration Complaint to Applicant as the first step to initiate a separate arbitration proceeding that will focus solely on the BetaVet issues raised in Petitioner's Citizen Petition. Petitioner wanted to make certain that the agency was aware of these procedural developments as it reviews and considers the issues raised in the Citizen Petition.

Please contact the undersigned with any questions.

Respectfully submitted,



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