DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

October 28, 2014

Jay S. Newman
Fish & Richardson, P.C.
1425 K Street, NW
11th Floor
Washington, DC 20005

Re: Docket No. FDA-2013-P-0862

Dear Mr. Newman:

This letter responds to your citizen petition dated July 12, 2013, submitted on behalf of Spec Pharma, LLC ("Petition"). The Petition requests, among other things, that FDA refrain from granting approval of the new animal drug application for BetaVet submitted in 2012 by Luitpold Pharmaceuticals, Inc. ("Luitpold"). We have carefully reviewed the Petition and the other information filed in the docket, which included the response dated September 23, 2013, filed by Peter S. Reichertz, on behalf of Luitpold Pharmaceuticals, Inc. ("Luitpold's Response") and the comment filed by you on October 16, 2013, on behalf of Spec Pharma, LLC. For the reasons described below, the Petition is denied.

I. BACKGROUND

In 2012, Luitpold submitted certain information from the approved abbreviated new drug application ("ANDA") for Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP (a human drug product referred to as "Beta Beta") to FDA's Center for Veterinary Medicine. This information was submitted to support the approval of a new animal drug application ("NADA") for BetaVet, a prescription new animal drug product.

On July 12, 2013, Spec Pharma, LLC ("Spec Pharma or petitioner") filed its Petition alleging that Luitpold had used or referenced data and materials from the approved Beta Beta ANDA without the petitioner's required authorization.[1] Specifically, Spec Pharma states that pursuant to an existing Development and Commercialization Agreement ("Agreement") between it and Luitpold, the parties agreed to joint ownership of the Beta Beta ANDA. Spec Pharma further states that the Agreement does not permit Luitpold to use any of the jointly-owned data or information to support the approval of an NADA for BetaVet without Spec Pharma's express consent. Spec Pharma also informed the agency that it and Luitpold are engaged in a formal arbitration proceeding regarding their respective ownership rights in the Beta Beta ANDA and

[1] In its Petition, Spec Pharma indicated that it first became aware of Luitpold's activities related to BetaVet on or about June 2013.

asserted its belief that the arbitration panel will confirm that Luitpold may not use or reference the data in the Beta Beta ANDA without Spec Pharma's consent.

Based on these allegations, Spec Pharma requests that FDA take the following specific actions:

• Refrain from granting approval of the BetaVet NADA until the arbitration panel determines Spec Pharma and Luitpold's ownership rights in certain data and information submitted or referenced in the BetaVet NADA.

• Advise Luitpold of the apparent deficiencies in its pending BetaVet NADA related to: (i) the improper use of or reference to certain data and information that is owned by Spec Pharma; and (ii) the improper certification of the BetaVet NADA.

• Refrain from granting approval of the BetaVet NADA without Spec Pharma's consent to use or rely on data and information relevant to the BetaVet NADA that the arbitration panel determines is owned by Spec Pharma.

In its response to the Petition, Luitpold acknowledges that it and Spec Pharma are parties to a formal arbitration proceeding regarding the ownership rights to the Beta Beta ANDA. Luitpold, however, asserts that it is the sole listed holder of record of the approved Beta Beta ANDA and that Spec Pharma has no legal interest in the ANDA or the application for BetaVet. Luitpold further asserts that the approval process should not be delayed based on its commercial dispute with Spec Pharma.

II. ANALYSIS

Based on the information submitted in your Petition and October 16, 2013, comment and Luitpold's Response, it appears that the parties are engaged in a commercial dispute regarding the ownership rights to the Beta Beta ANDA. In particular, the parties disagree as to whether Luitpold may use or reference information and data contained in the Beta Beta ANDA for the purpose of seeking approval of BetaVet without the express consent of Spec Pharma. You informed the agency, and Luitpold in its response confirmed, that Spec Pharma and Luitpold are parties to a formal arbitration proceeding, the purpose of which is to resolve the parties' respective ownership rights to the Beta Beta ANDA.

In response to a previous citizen petition filed by another party raising similar issues, we noted that the agency's records indicated that the applicant had authority to use the disputed data and that any dispute over the ownership of the data was "more appropriately resolved" in the private lawsuit that was then pending between the parties rather than by the agency in an administrative proceeding.[2] See FDA's May 9, 1983, Response to Citizen Petition submitted by A.L. Laboratories, Inc., Docket No. 82P-0297.[3]

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[2] Because it is not appropriate for the agency to opine on the meaning of the provisions in the parties' private commercial agreement, we do not address those arguments in this response. The meaning of the terms of the parties' commercial agreement is more appropriately determined by the arbitration panel and any subsequent appeals.

[3] The agency's response to the earlier citizen petition is also discussed in A.L. Pharma, Inc. v. Shalala, 62 F.3d 1484, 1488 (D.C. Cir. 1995), one of the cases cited in Spec Pharma's Petition.

The agency recently conducted a search of its records and, based on that search, has confirmed that Luitpold is the applicant of record for the Beta Beta ANDA (Application No. A090747). See Orange Book[4] entry at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=090747&TABLE1=OB_Rx

In addition, Luitpold submitted a signed FDA Form 356v in connection with its submission of certain information from the approved Beta Beta ANDA. The FDA Form 356v includes certain certifications made on behalf of the applicant. When Luitpold submitted this form to CVM it certified that, to the best of its knowledge and belief, the information and representations made in its submission were true, accurate, and complete. See FDA Form 356v at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/UCM048749.pdf

CVM, in accordance with agency policy, relies on the certifications contained in the FDA Form 356v when it accepts a submission for review. To do otherwise would undermine the efficiency of the agency's review processes. For example, as set forth in the Animal Drug User Fee Amendments of 2013 ("ADUFA III") and Animal Generic Drug User Fee Amendments of 2013 ("ADUFA II") respective goals letters, the agency agreed to meet specific review timeframes for certain NADA and abbreviated new animal drug application ("ANADA") submissions. If the agency is not able to rely on the certifications contained in the FDA Form 356v, significant delays in the review process may occur, and the Agency may be unable to meet its obligations under the ADUFA III and AGDUFA II goals letters. See, http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM343226.pdf, http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/UCM343235.pdf

Your Petition refers to several federal court cases in support of Spec Pharma's position that 21 CFR § 514.1(a)[5] and the instructions in the FDA Form 356v prevent the agency from relying on data from the Beta Beta ANDA without Luitpold first obtaining Spec Pharma's consent. However, Spec Pharma's reliance on the cases it cites for this proposition is misplaced because the cases involve situations in which the data relied upon by the applicant were furnished to FDA by a person other than the applicant (i.e., by a "third party"). Here, the applicant itself (Luitpold) furnished the data at issue. For this same reason, Spec Pharma cannot rely on 21 CFR § 514.1(a)

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[4] The publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies human drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act.

[5] The specific language of 21 CFR § 514.1(a) cited by Spec Pharma provides as follows:
"Pertinent information may be incorporated in, and will be considered as part of, an application on the basis of specific reference to such information, including information submitted under the provisions of §511.1 of this chapter, in the files of the Food and Drug Administration; however, the reference must be specific in identifying the information. Any reference to information furnished by a person other than the applicant may not be considered unless its use is authorized in a written statement signed by the person who submitted it."

and the instructions of the FDA Form 356v to support its position that Luitpold needed a right of reference from Spec Pharma before it could use this data to support the approval of BetaVet.

Based on the certifications provided by Luitpold in its signed FDA Form 356v, as well as the fact that Luitpold is listed as the applicant of record for the Beta Beta ANDA, the agency will move forward with its review of Luitpold's pending submissions related to its application for the approval of BetaVet.[6]

If Luitpold wants FDA to put the review process on hold until the arbitration panel determines Spec Pharma and Luitpold's ownership rights with respect to the data and information in the Beta Beta ANDA, it may make such a request at its own discretion.

III. CONCLUSION

For the reasons described in this response, the Petition is denied.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine

cc: Peter S. Reichertz

[6] Once the agency determined that it can consider the data in the Beta Beta ANDA to support the approval of BetaVet, Spec Pharma's arguments related to the applicability of 21 CFR § 514.100(a) became moot.