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VIA HAND DELIVERY

July 12, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition under Section 505 of the Federal Food, Drug, and Cosmetics Act (the "Act") (21 U.S.C § 355) and 21 C.F.R. §10.30, among other provisions of law, on behalf of Spec Pharma, LLC ("Petitioner") which markets, sells and distributes a prescription pharmaceutical product known as Beta Beta (as discussed below). Petitioner requests that the Commissioner of Food and Drugs take the actions described below with respect to the New Animal Drug Application for BetaVet ("BetaVet NADA") submitted in 2012 by Luitpold Pharmaceuticals, Inc. ("Applicant") or one of its affiliated companies.[1] BetaVet is a corticosteroid drug for the treatment of inflammation.

On information and belief, the BetaVet NADA contains relevant data and materials owned by Petitioner which cannot be used or relied on by Applicant in support of the BetaVet NADA without Petitioner's express consent (which Petitioner has not given). Specifically, Applicant recently confirmed to Petitioner (after Petitioner had tentatively concluded on its own) that the BetaVet NADA includes and/or references data and materials from the chemistry, manufacturing and controls ("CMC") section of the approved Abbreviated New Drug Application ("ANDA") for Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP (referred to as "Beta Beta").[2] Petitioner has specific ownership rights in Beta Beta (which is the human drug version of BetaVet) pursuant to a contract between Petitioner and Applicant. Petitioner and Applicant currently are engaged in a formal arbitration proceeding regarding their

[1] Petitioner is unsure whether the Beta Vet NADA was submitted to FDA in the name of Luitpold Pharmaceuticals, Inc., American Regent, Inc. (which is an affiliate of Applicant) or some other affiliated entity. For purposes of this Citizen Petition, we have assumed that Luitpold Pharmaceuticals, Inc. is the applicant. Even if one of its affiliates is the applicant, the same analysis set forth herein would apply.

[2] The National Drug Code numbers for Beta Beta are NDC# 40042-048-05 (which is in the labeler name, PharmaForce, Inc., a company that became wholly owned by Applicant pursuant to a 100% stock acquisition in December 2009) and NDC# 0517-0720-0 (which is in the labeler name, American Regent, Inc., an affiliate of Applicant). The drug was approved July 31, 2009 under ANDA090747.

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respective rights and interests in Beta Beta including the data underlying the ANDA approval. Petitioner believes that the arbitration panel will confirm Petitioner's ownership rights in this data and thereby, establish that Applicant has used or referenced such data in the BetaVet NADA without Petitioner's required authorization. The unauthorized use of such data not only misappropriates Petitioner's property rights, but also circumvents FDA rules and policies that are designed to protect ownership rights in data submitted or referenced in drug applications.

A. ACTIONS REQUESTED

- That FDA refrain from granting approval of the BetaVet NADA until the arbitration panel determines Petitioner's and Applicant's ownership rights in certain data and information submitted or referenced in the BetaVet NADA.

- That FDA advise Applicant 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 Petitioner; and (ii) the improper certification of the BetaVet NADA.

- That FDA refrain from granting approval of the BetaVet NADA without Petitioner's consent to use or rely on data and information relevant to the BetaVet NADA that the arbitration panel determines is owned by Petitioner.

B. STATEMENT OF GROUNDS

1. Petitioner believes that Applicant is using and/or referencing data and information relevant to its BetaVet NADA that is owned by Petitioner and that such ownership rights will be confirmed pursuant to the current arbitration proceeding between the parties.

In March 2004, PharmaForce, Inc. (which was acquired by Applicant in December 2009 whereby Applicant assumed all rights and obligations of PharmaForce, Inc.) and Petitioner entered into a Development and Commercialization Agreement ("Agreement") with respect to the formulation, development, manufacturing, sales, marketing and distribution of drugs which currently includes Beta Beta. Pursuant to the Agreement, the parties agreed to joint ownership of the formula, manufacturing specifications and ANDA for the Beta Beta drug product. A dispute has arisen between Petitioner and Applicant regarding their ownership and other interests, resulting in the current arbitration proceeding.

Applicant recently disclosed to Petitioner that it had submitted the BetaVet NADA without Petitioner's knowledge or consent. Applicant also disclosed that the BetaVet NADA included certain data and information from the CMC section of the Beta Beta ANDA and that the complete ANDA was submitted to the NADA file in response to an FDA request. Petitioner was not consulted on the BetaVet NADA and has never given its consent for any data or information associated with the Beta Beta ANDA to be used or referenced in the BetaVet NADA.

Prior to Applicant's disclosures to Petitioner regarding the use of the Beta Beta ANDA data, Petitioner asked its medical expert, Dr. Samir Patel, who was intimately involved in the development of Beta Beta, to analyze the similarities and differences between the Beta Beta and BetaVet products. Dr. Patel concluded that the BetaVet NADA likely incorporates data and information from the Beta Beta ANDA that are necessary for BetaVet's approval.

Petitioner contends that the Agreement does not permit Applicant to use any jointly-owned data or information for an NADA submission without Petitioner's express consent. [redacted] Accordingly, Applicant has no authority to use or reference such data or information in the pending BetaVet NADA for its own

[3] [redacted]

[4] [redacted]

benefit without first obtaining Petitioner's consent. Petitioner will be asking the arbitration panel to confirm Petitioner's ownership rights in the Beta Beta ANDA along with the underlying data and information; and further, to confirm that Applicant's rights under the Agreement do not include the use of, or reference to, such data in support of the BetaVet NADA without Petitioner's written consent.

2. **Consistent with FDA rules, policies and the NADA submission instructions, Applicant may only rely on data and information to which it has a right of reference.**

   a. **The legal standard for NADA submissions is based on a policy that recognizes and protects a party's property interests in the data that it owns.**

As a threshold matter, FDA may not consider referenced information furnished by third parties in support of an NADA without the third party's written consent. Specifically, 21 C.F.R. § 514.1(a) reads, in part:

> 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.[5]

"By its terms, [21 C.F.R. § 514.1(a)] prevents the agency from using data submitted by one party for the benefit of another without the permission of the submitter."[6] The limited case law involving this regulation generally focuses on situations where one party submits data to FDA, and another party later files an NADA that references the first party's data without the first party's consent.[7] Here, the Applicant submitted relevant data from the Beta

[5] 21 C.F.R. § 514.1(a) (emphasis added).

[6] *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1489 (D.C.Cir. 1995) (interpreting 21 C.F.R. § 514.1(a)).

[7] *See, e.g., Tri-Bio Laboratories, Inc. v. United States of America and Food and Drug Administration*, 836 F.2d 135 (3rd. Cir. 1988).

Beta ANDA for which it may be the listed owner of record from an FDA perspective yet, that tells only part of the story. What Applicant failed to disclose to FDA is that the ANDA data is jointly owned and governed by an Agreement that requires Petitioner's consent for such data to be used or referenced in an NADA application.[8] Case law teaches that such data do not become general knowledge after development and submission to FDA, but rather, that "each subsequent applicant must obtain the data at its own expense."[9] The fact that the Applicant may have had the right to use certain data in support of an ANDA does not mean that it automatically has the right to such data in support of a subsequent NADA. Applicant's right to use of such data must be established with every FDA submission.

Even though there might be some ambiguity in the wording of §514.1(a), it must be read to apply to Petitioner's situation. Specifically, the regulation distinguishes between information "furnished" by a person and information "submitted" by a person. Under the parties' Agreement, jointly owned information is "furnished" for use by the Applicant but only to the extent that Petitioner consents to it being "furnished." Thus, if Petitioner does not consent to Applicant using or referencing the Beta Beta ANDA data outside the Agreement, it cannot legally be "furnished" for use in the BetaVet NADA. By providing the full Beta Beta ANDA, however, Applicant is representing to FDA that it has the right to use and reference the ANDA data in support of the BetaVet NADA (which is inconsistent with the Agreement). While FDA might initially presume Applicant to have such rights based on representations at the time of NADA submission, Petitioner's ownership claims now raise material concerns that require resolution in arbitration before FDA should act on the NADA.

Further evidence of FDA's policy of protecting a data owner's property rights is set forth in the instructions for NADA Form FDA 356v.

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[8] The fact that Applicant submitted data to FDA does not mean that Applicant has unfettered or unlimited rights to the data. *See, e.g., A.L Laboratories, Inc. v. Philips Roxane, Inc.*, 803 F.2d 378, 384 (8th Cir. 1986) ("We read the district court's opinion as referring merely to the manner in which the data came to be in an FDA file in Philips Roxane's name, an occurrence which, as we stated earlier, could not increase Philip Roxane's rights in the study results.").

[9] *A.L. Laboratories,* 803 F.2d at 380 (holding that unauthorized use of data in an NADA amounted to misappropriation of trade secrets). *See also*, *Tri-Bio Laboratories*, 836 F.2d at 139-141 (holding that section 514.1(a) creates a property interest in data that is furnished by a person other than the applicant, and the use of such data without consent constitutes a Fifth Amendment taking, requiring FDA to not consider such data); and *A.L. Pharma*, 62 F.3d at 1489 (citing *Tri-Bio*) (holding that section 514.1(a) provides pioneering animal drug manufacturers with a reasonable expectation that their research and development investments will not inure to the benefit of their competitors).

REDACTED

The form requires an applicant that does not "own" data or information referenced in another file to ensure that it possesses the appropriate authorization to reference such data. Specifically, the form's instructions state: "If you reference data or information in any file you don't own, make sure a copy of your authorization to reference such data or information is included with your submission or has already been submitted to the file in which you referenced it."[10] Although there is some ambiguity in the instruction, Petitioner believes that the phrase "you don't own" modifies "data or information," and that it does not modify "file" since FDA technically "owns" such files.[11] Moreover, while Applicant may have an ownership interest in the contested data and information, this does not mean it has the necessary ownership interest to use unilaterally the data and information as it pleases.[12] Underlying § 514.1(a) and the Form 356v instructions is the policy that an applicant must truthfully and accurately represent whether a third party has an ownership interest in the referenced data and information and, if a third party has such an interest, the applicant must have authorization to use or reference such data and information.

b. This legal standard and its underlying policy objective support Petitioner's request for FDA to refrain from granting Applicant's NADA until the arbitration panel clarifies the parties' ownership interests in the Beta Beta ANDA and underlying data and information.

With respect to the Beta Beta ANDA filed years ago, PharmaForce, Inc. submitted the currently contested data and information in its own name as part of the ANDA pursuant to the Agreement and with Petitioner's consent. However, the Agreement allocates ownership rights in the data (and the Beta Beta ANDA) to Petitioner and Applicant whereby Applicant does not have unfettered rights to use this data (and the Beta Beta ANDA) to support the BetaVet NADA. Specifically, Applicant must obtain Petitioner's consent before using data to support the BetaVet NADA. Petitioner understands that it is not FDA's responsibility to determine ownership rights to data submitted to it and leaves that determination to the arbitration panel in the pending proceeding.[13] However, it would be contrary

[10] Form FDA 356v at p. 5.

[11] Section 514.1(a) refers to "in the files of the Food and Drug Administration," implying that FDA maintains ownership of these files.

[12] *See, e.g., A.L. Laboratories,* 803 F.2d at 382 ("The relative rights [of the parties] … to the … study data are governed by the relationships among those companies… .").

[13] "[A]ny dispute over the ownership of [cross referenced] information was 'more appropriately resolved' in a civil suit . . . than in an administrative proceeding." *A.L. Pharma*, 62 F.3d at 1488

to the FDA policy objectives underlying § 514.1(a) and the NADA instructions for FDA to grant the BetaVet NADA at this time given the uncertainty regarding Applicant's authority to use the contested data and information associated with the Beta Beta ANDA.

In light of the public policy at issue here, and the potential misappropriation by Applicant of Petitioner's property rights, Petitioner requests that FDA refrain from granting Applicant's NADA until the arbitration panel confirms the ownership interests discussed herein. Petitioner anticipates a decision by the arbitration panel within approximately six (6) months— which is a relatively short time period to determine whether there has been a significant violation of Petitioner's property rights. Furthermore, this approach avoids the possibility of FDA having to withdraw a premature grant because the arbitration panel subsequently confirms Petitioner's position.

To be clear, Petitioner is not asking FDA to dismiss or reject the BetaVet NADA at this time. Rather, Petitioner is asking FDA to withhold any approval decision on the BetaVet NADA until the arbitration panel confirms the ownership interests in the contested data and information that may be relevant to FDA approval.

3. Petitioner further requests that FDA refrain from granting the BetaVet NADA until the arbitration panel issues a decision because Applicant's NADA suffers from multiple "apparent deficiencies."

Title 21 C.F.R. § 514.100(a) states, "after the filed application has been evaluated, the applicant will be furnished written comment on any apparent deficiencies in the application." This regulation allows FDA to notify Applicant of apparent deficiencies related to the Beta Beta data and information used or referenced in the NADA and to consider granting the NADA only after those deficiencies are resolved. Petitioner has identified a number of apparent deficiencies in Applicant's NADA including the following:

a. Data was Used and/or Referenced Without Petitioner's Consent. The Agreement established Petitioner's property rights in the Beta Beta ANDA and its underlying data. The Agreement also established that such property rights can only be used or relied on with Petitioner's consent. The FDA policy underlying §514.1(a)

(citing FDA response to citizen petition that argued ownership of safety data relied upon by an NADA applicant).

REDACTED

requires, in this instance, that Petitioner's consent be obtained before the Beta Beta ANDA or any of its underlying data be used or referenced in Applicant's NADA.

b. NADA is Incomplete, False and/or Inaccurate. Form FDA 356v requires Applicant to include a copy of the authorization from the owner of any third party data referenced in support of an NADA. Petitioner acknowledges that an "instruction" on an application form does not hold the same legal significance as a statute, regulation, or relevant judicial and administrative interpretations. However, the instruction is part of a submission upon which the Applicant certifies that the contents are "true, accurate and complete."[14] Failure to include required proof of authorization to use Petitioner's data in the application is an apparent deficiency of Applicant's NADA (verified upon arbitration decision) and results in, at best, an incomplete application and, at worst, a false and/or inaccurate application.[15]

c. Applicant Submitted Insufficient Data for FDA to Grant Approval At This Time. Finally, without Petitioner's data, Petitioner strongly suspects that FDA will be unable to make a safety and efficacy determination on which to base a grant and thereby, resulting in an incomplete NADA submission.[16] Therefore, an apparent deficiency of Applicant's NADA (verified upon arbitration decision) is the possibility of insufficient data within the Applicant's NADA upon which to base a grant.

Therefore, pursuant to 21 C.F.R. § 514.100(a), FDA should advise Applicant of these apparent deficiencies in its application, all of which will be clarified upon determination of the arbitration panel. If the arbitration panel confirms Petitioner's ownership rights discussed herein, then FDA should advise Applicant that it cannot grant its NADA until Applicant (i) obtains Petitioner's written consent to use or reference the data and information at issue, and (ii) amends or supplements its BetaVet NADA accordingly.

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[14] Form FDA 356v at p. 3.

[15] Arguably, Applicant also could be found to have acted in bad faith by filing the BetaVet NADA which cross-references the contested data and information to the extent it was aware of a potential dispute with Petitioner regarding the parties' ownership rights in the contested data and information. *See A.L. Laboratories, Inc. v. Philips Roxane, Inc.*, 803 F. 2d, at 384 ("...jury could have found bad faith in Philips Roxane's failure to even question its initial 'acquisition' of the information").

[16] *See also* 21 C.F.R. § 514.111(a) (4) (insufficient information to determine drug safety is a reason for refusal to approve an NADA).

REDACTED

C. ENVIRONMENTAL IMPACT STATEMENT

The specific action requested by Petitioner will not increase the use of the drug. Therefore, it is categorically excluded from the requirement of environmental documentation under 21 C.F.R. §§ 25.33(a).

D. ECONOMIC IMPACT STATEMENT

The requested information is only required when requested by the Commissioner following the review of the Petition and, therefore, an economic impact statement is not provided at this time.

E. CERTIFICATION

We certify that, to our best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the Petitioner which are unfavorable to the petition; and (c) we have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to us. We further certify that the information upon which we have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about June 2013. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: None, other than my compensation as outside counsel for Petitioner. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Respectfully submitted,

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