

2038 03 NOV --6 AM '03

WRITER'S DIRECT ACCESS

November 6, 2003

**John B. Dubeck**  
(202) 434-4125  
Dubeck@khlaw.com

**Via Hand Delivery**

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

**Re: Docket No. 2003N-0324; Support for Alharma's Request for Hearing**

Dear Sir or Madam:

Alharma Inc. (Alharma) hereby provides this submission in support of its Request for Hearing (dated September 8, 2003), in response to the Food and Drug Administration's (FDA) Notice of Opportunity for Hearing (NOOH) in connection with proposed withdrawal of various new animal drug applications (NADAs) for certain products or use combinations lacking substantial evidence of effectiveness.<sup>1</sup> Alharma's interest is with respect to the legal status of NADA 141-137 for Pennitracin MD 50 (bacitracin methylene disalicylate (bacitracin MD)), purportedly held by Pennfield Oil Co./Pennfield Animal Health (Pennfield). Pennfield submitted its own Request for Hearing dated September 8, 2003.

The NOOH stated that this proceeding applies to "all issues relating to the legal status of the drug products subject to" the notice.<sup>2</sup> Alharma is participating in this proceeding to ensure that it is not precluded from raising objections to Pennfield's bacitracin MD product.

Pennfield's Request asserts "four nonexclusive arguments why Pennfield has lawful approval" for the entire collection of bacitracin MD claims listed in 21 C.F.R. § 558.76 (Pennfield Request at 2). Even assuming that Pennfield has an approval (which Alharma disputes, as discussed below), none of Pennfield's arguments raises issues that warrant a hearing. As a result, FDA should promptly withdraw the claims for bacitracin MD as proposed in the NOOH.

<sup>1</sup> 68 *Fed. Reg.* 47332 (August 8, 2003). FDA extended until November 6, 2003, the deadline for parties who had requested a hearing to submit data and analyses in support of the hearing requests. 68 *Fed. Reg.* 57911 (October 7, 2003).

<sup>2</sup> 68 *Fed. Reg.* 47339.

It is Alharma's belief that Pennfield is not entitled to market a bacitracin MD product with even the "DESI-effective" claims identified in Table 1 of the NOOH.<sup>3</sup> There is insufficient evidence in the record to establish that Pennfield (and its predecessors) ever had the requisite "product approval" that was a condition precedent to enjoying the "interim marketing rights" formalized by 21 C.F.R. § 558.15. If a predicate approval is not documented, Pennfield should not be allowed to market a bacitracin MD product unless and until it has submitted and received specific FDA approval of an application submitted under Section 512 of the Federal Food, Drug, and Cosmetic Act.

Whether a predicate approval was ever held by Pennfield's predecessors is a question of fact. If there is conflicting evidence on this issue, Alharma requests that FDA grant a hearing solely to establish whether Pennfield's predecessors had the required bacitracin MD product approval as of the threshold date (*i.e.*, as of August 1, 1969) required for inclusion in the sponsor list in 21 C.F.R. § 558.15. Since this issue is independent of what claims may be permitted, FDA should move immediately to deny Pennfield's request for a hearing and withdraw Pennfield's approval for all bacitracin MD claims other than those found to be DESI-effective.

#### **I. The Pennfield Request Does Not Show That A Hearing Is Necessary**

Despite filling 26 pages with its protestations, Pennfield's "four nonexclusive arguments" ultimately boil down to a disagreement over the proper interpretation and implementation of FDA's animal drug regulations. While the merits of different policies may be open for debate, this disagreement simply does not involve any genuine or substantial issue of fact. FDA should deny Pennfield's request for a hearing on all four arguments.

Similarly, there is no need for the submission of additional documents or information to be considered during a hearing. Pennfield asserts that it "has submitted sufficient evidence through the years to provide a complete administrative record documenting full approval for all claims the company is currently making under NADA 141-137, both DESI and post-DESI," – a record that Pennfield claims is "incontestable" (Pennfield Request at 15). Pennfield's later claim that "extensive administrative discovery is required" (Pennfield Request at 22) simply rings hollow.

Alharma's comments on Pennfield's four grounds for requesting a hearing are presented below.

---

<sup>3</sup> 68 *Fed. Reg.* at 47333.

- A. “Pennfield’s predecessor in interest, Fermenta, is listed as a sponsor of [bacitracin MD] in § 558.15, and FDA’s position that the Agency erred by not clarifying its regulatory provisions should not inure to Pennfield’s detriment” (Pennfield Request at 3, 12)

This argument raises purely legal claims and does not suggest that any genuine or substantial issue of fact is in dispute or justifies a hearing. Indeed, there is no dispute over the language of the regulations in question. The sole issue is the proper interpretation of that language – a function that is purely legal in nature. FDA has already rejected Pennfield’s broad interpretation when the Agency stated that it was “not aware of any additional approved indications beyond those listed in the original § 558.76 from 1976 for Pennfield Oil Co.’s product” (underlining added).<sup>4</sup>

Even taken at face value, Pennfield’s simplistic argument is not persuasive. Alpharma acknowledges that 21 C.F.R. § 558.15(g)(1) cross-references § 558.76 without qualification. However, the table in § 558.76 includes a column entitled “Sponsor.” The one and only “Sponsor” identified for each claim listed in the table is “046573.” This unique sponsor number is associated solely with Alpharma Inc.<sup>5</sup> Interestingly, Pennfield has its own recognized sponsor number (053389),<sup>6</sup> yet this number does not appear anywhere in § 558.76.

Pennfield’s insistence on reading the literal language of the regulations suddenly becomes less persuasive when the regulations are read in full. Not surprisingly, Pennfield’s Request fails to note this inconvenient fact or to explain how Pennfield can be viewed as having approval for the full panoply of bacitracin MD claims when only Alpharma is identified as a Sponsor of those claims. The clear answer is that the regulations are subject to interpretation – a legal and discretionary issue that cannot justify a request for a hearing.

- B. “FDA’s letter to BIV [Boehringer Ingelheim Vetmedica], Pennfield’s immediate predecessor in interest, indicating the company had lawful approval of NADA 141-137” (Pennfield Request at 4, 13)

Pennfield’s arguments misconstrue the purpose of the “certification” exercise FDA went through in the summer of 1998. A sponsor’s listing in 21 C.F.R. § 558.15 reflected FDA’s conclusion that the drug identified was approved prior to the effective date of the Animal Drug Amendments of 1968. Indeed, FDA stated in 1976 that “only drugs and sponsors which the Commissioner has determined to be approved for use by NADA, NDA, master file, antibiotic

---

<sup>4</sup> 68 *Fed. Reg.* at 47334.

<sup>5</sup> 21 C.F.R. § 510.600(c)(1).

<sup>6</sup> *Id.*

regulation, or food additive regulation have been listed” in § 558.15.<sup>7</sup> The letters FDA sent in 1998 to various sponsors were intended to shore up the Agency’s inadequate records to document the existence of the approval at the time regulation was finalized.<sup>8</sup> This action did no more than maintain the *status quo*; it did not purport to expand the scope of any of the approvals that allegedly existed.

Thus, any letter Pennfield received from FDA did not, and could not, “verify the approved status” of an NADA for bacitracin MD for any claims beyond those existing at the time the list in 21 C.F.R. § 558.15 was finalized (*i.e.*, February 25, 1976). Once again, the issue boils down to the proper interpretation of FDA’s regulations – a legal interpretive function that does not warrant an administrative hearing.

In any case, BIV apparently did not have nearly as much confidence in the scope of its alleged approval as Pennfield does. In a surprising request for a company that supposedly had long-existing approval, in July 1998 BIV sought FDA’s help in confirming the most important aspect of any such approval – the claims. BIV asked FDA:

Specifically, what are the current labeling claims for the interim marketed Bacitracin [MD] Type A Medicated Article: (1) claims prior to DESI finalization, (2) claims reflecting DESI finalization or (3) claims currently codified in 21 CFR 558.76 and 21 CFR 510.515?<sup>9</sup>

Pennfield’s assertion that FDA’s letter “reaffirmed” that it had approval for all of the claims listed in 21 C.F.R. § 558.76 seems nonsensical in this context.

- C. “GADPTRA and CVM’s implementing policy letters demonstrate that Pennfield has approval for all the claims in question” (Pennfield Request at 4, 16)

Pennfield goes to great lengths to discuss the Generic Animal Drug and Patent Term Restoration Act of 1988 (GADPTRA) and how these provisions would allow an applicant to seek FDA approval of a version of bacitracin MD. Even assuming that Pennfield’s characterizations of the statute are correct (and Alpharma does not concede that they are), these arguments are irrelevant for purposes of the NOOH for one simple reason: Pennfield has not followed these procedures. Pennfield’s alleged approval for NADA 141-137 is based on a

---

<sup>7</sup> 41 *Fed. Reg.* 8282, 8285 (February 25, 1976) (FDA response to comment 6).

<sup>8</sup> Letter from Stephen F. Sundlof, Director of Center for Veterinary Medicine, to BIV (dated July 29, 1998) (obtained under the Freedom of Information Act (FOIA)) (copy enclosed as Attachment A), at page 1 – 2.

<sup>9</sup> Letter from Donald A. Gable, BIV, to FDA (dated July 16, 1998) (obtained under FOIA) (copy enclosed as Attachment B), at page 3.

“certification” process conducted through correspondence with FDA in 1998 (Pennfield Request at 13 - 16). Nowhere does Pennfield suggest that this exchange of correspondence satisfied the GADPTRA requirements. Rather, FDA solicited the certification to “establish[] that an approval corresponding to a specific listing in section 558.15 was granted prior to the February 25, 1976, publication date of 21 C.F.R. § 558.15.”<sup>10</sup>

In short, the certification FDA requested was to confirm an already-existing approval for bacitracin MD. The scope of the claims permitted for that approval, as noted above, is a legal issue that turns on the proper interpretation of FDA’s regulations. Whatever approval Pennfield may be able to obtain under GADPTRA is irrelevant; this statute does not expand the scope of existing approvals in the absence of any effort by a sponsor to follow the procedures that GADPTRA established.

- D. “Any three-year exclusivity period was [sic] enjoyed by AL Labs/Alpharma has since expired” (Pennfield Request at 6, 18)

Alpharma admits that three years have passed since the last NADA supplement approved by FDA concerning Alpharma’s bacitracin MD. Of course, the expiration of any exclusivity does not raise any factual issues with respect to the ability of FDA to approve other products, should such an application be submitted. Pennfield’s argument does not suggest any genuine or substantial issue of fact in dispute that justifies a hearing.

**II. At Most, A Hearing May Be Required To Determine Whether Pennfield’s Predecessors In Interest Actually Held An “Approval” Required to Qualify For “Interim Marketing Rights” Under 21 C.F.R. § 558.15**

A careful examination of the administrative record with respect to bacitracin MD and Pennfield’s alleged approval shows that Pennfield never had a required “approval” as of the effective date of the Animal Drug Amendments of 1968 (a prerequisite for eligibility for the “interim marketing rights”). In the absence of this approval, Pennfield is not entitled to market a bacitracin MD product with even the DESI claims outlined in the NOOH. A detailed review of this evidence is contained in Citizen Petition Docket No. 2003P-0517 and the corresponding attachments (submitted by Alpharma on November 5, 2003). A copy of this petition is provided as Attachment C and is hereby incorporated by reference into the NOOH administrative proceedings.

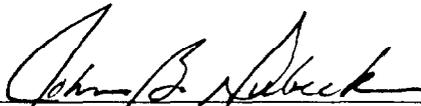
None of the arguments in Pennfield’s Request justifies a hearing. Alpharma believes the record is clear that there is insufficient information to establish that Pennfield is eligible for the “interim marketing rights” documented in 21 C.F.R. § 558.15. As a result, FDA should conclude that Pennfield is not eligible to market a bacitracin MD product with any claims. Unless FDA

---

<sup>10</sup> Letter from Stephen F. Sundlof (dated July 29, 1998) (Attachment A), at page 2.

agrees that Pennfield never had a pre-1969 approval, Alharma requests that the Agency grant a hearing solely on this issue.

Respectfully submitted,



John B. Dybeck  
Frederick A. Stearns  
Keller and Heckman LLP  
1001 G Street, N.W., Suite 500W  
Washington, D.C. 20001  
(202) 434-4200

Counsel for Alharma Inc.

Attachments:

- A. Letter from Stephen F. Sundlof to BIV (dated July 29, 1998).
- B. Letter from Donald A. Gable, BIV, to FDA (dated July 16, 1998).
- C. Citizen Petition Docket No. 2003P-0517 (submitted November 5, 2003).