KELLER AND HECKMAN LLP
SERVING BUSINESS THROUGH LAW AND SCIENCE®

1001 G STREET, N. W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TEL. 202.434.4100
FAX 202.434.4646
WWW.KHLAW.COM

3009 '03 -5 12:00

WRITER'S DIRECT ACCESS

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

November 5, 2003

Via Hand Delivery

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

CITIZEN PETITION

On behalf of our client, Alpharma Inc., the undersigned submits this Citizen Petition under 21 C.F.R. § 10.30 and section 512 of the Federal Food, Drug, and Cosmetic Act (FDC Act) to request that the Commissioner of Food and Drugs find that Pennfield Oil Company (Pennfield) is not now, and never has been, eligible for "interim marketing" rights under 21 C.F.R. § 558.15 for bacitracin methylene disalicylate (bacitracin MD) as a Type A medicated article for use in animal feed.

ACTION REQUESTED

Alpharma requests that the Commissioner determine that Pennfield is not now, and never has been, eligible for "interim marketing" rights under 21 C.F.R. § 558.15 for bacitracin MD. As demonstrated below, the Food and Drug Administration (FDA) does not have sufficient information to show that Pennfield (or its predecessor companies) ever had an appropriate approval of a bacitracin MD product. The Agency's initial conclusion was based on a self-serving representation by a company official for which no supporting documentation exists. As a result, FDA must find that Pennfield never had any "interim marketing" rights to bacitracin MD and, consequently, is not entitled to market bacitracin MD with claims determined to be effective under the Drug Efficacy Study Implementation (DESI) process.

STATEMENT OF GROUNDS

A. Background: FDA's Records Do Not Support Pennfield's Eligibility for Interim Marketing Rights

On August 8, 2003, FDA published a Notice of Opportunity for Hearing (NOOH) proposing the withdrawal of various claims for bacitracin MD that FDA has found to be lacking

substantial evidence of effectiveness.[1] The NOOH purports to apply to a bacitracin MD product which FDA has identified as being covered by New Animal Drug Application (NADA) 141-137, held by Pennfield.[2] The NOOH coincides with FDA's separate proposal to remove 21 C.F.R. § 558.15,[3] which currently lists those animal drugs for which the sponsors had made commitments in the early 1970s to generate additional data about the long-term safety about the use of antibacterial animal drugs for subtherapeutic or growth promotion purposes.

The relevant listing in 21 C.F.R. § 558.15 of companies and products was originally finalized in 1976.[4] At the time of publication, FDA stated that "only drugs and sponsors which the Commissioner has determined to be approved for use by NADA, NDA, master file, antibiotic regulation, or food additive regulation have been listed."[5] Under section 108 of the Animal Drug Amendments of 1968, an animal feed product which had been approved under one of these mechanisms before August 1, 1969 was deemed to be the subject of an approved NADA under Section 512 of the FDC Act.[6] A valid approval of one of these forms was required for the product to be eligible for any marketing; 21 C.F.R. § 558.15 established criteria that had to be

---

1 68 *Fed. Reg.* 47332 (August 8, 2003). This document also established certain limited claims for bacitracin MD single-ingredient medicated articles, which FDA found to be effective based on the recommendations of the National Academy of Sciences/National Research Council review. *See* 35 *Fed. Reg.* 11531 (July 17, 1970), as corrected by 35 *Fed. Reg.* 15408 (October 2, 1970).

2 The existence of NADA 141-137 was disclosed in late 2000. On June 11, 2001, Alpharma submitted a request under the Freedom of Information Act (FOIA) for records pertaining to any applications held by Boehringer Ingelheim Vetmedica Inc. (BIVI) or predecessor companies for the use of bacitracin MD in animal feeds, including the following: (1) any information regarding the circumstances of the listing in 21 C.F.R. § 558.15 for BIVI as a sponsor entitled to interim marketing provisions of that regulation; (2) information submitted to substantiate interim marketing and to meet the data requirements of 21 C.F.R. § 558.15; and (3) Freedom of Information Summary (or basis of approval) and labels for NADA 141-137. Alpharma received a response to this request on March 18, 2003. Given the comprehensive nature of Alpharma's request, Alpharma believes that the response reflects the administrative record of the rulemaking proceeding as it relates to the inclusion of BIVI's bacitracin MD in 21 C.F.R. § 558.15.

3 68 *Fed. Reg.* 47272 (August 8, 2003).

4 41 *Fed. Reg.* 8282 (February 25, 1976).

5 *Id.* at 8285 (FDA response to comment 6).

6 Sec. 108, P.L. No. 90-399, 82 Stat. 482 (1968). The statute was signed into law on July 13, 1968 and became effective "on the first day of the thirteenth month which begins after the date of enactment of this Act." Approvals in effect at that time were subject to modification or revocation pursuant to the provisions of Section 512 of the FDC Act.

met to prevent FDA from extinguishing the "interim marketing" rights, but the regulation could not otherwise create such rights.

As FDA noted recently, however, many years after the publication of § 558.15, "it became apparent that the administrative record associated with 15 products was incomplete, calling into question their approval status."[7] As demonstrated below, FDA does not have sufficient information to show that Pennfield (or its predecessors[8]) had an appropriate approval prior to August 1, 1969. As a result, Pennfield's bacitracin MD product was never eligible for the "interim marketing" rights created by the Animal Drug Amendments of 1968; compliance with the data generation provisions of 21 C.F.R. § 558.15 is irrelevant. Consequently, Pennfield is not eligible for the limited DESI claims that FDA has determined are effective for bacitracin MD.

The administrative record is replete with references to the inability of FDA and Pennfield's predecessors to document that the bacitracin MD product was, in fact, approved prior to August 1, 1969. FDA has improperly relied on incomplete representations from Pennfield and its predecessors to permit the marketing of Pennfield's bacitracin MD. The basis for this conclusion is presented below.

B. Publication of 21 C.F.R. § 558.15 Asserts Eligibility With Only Scant Evidence

On August 6, 1974, FDA published a notice of proposed rulemaking as part of its efforts to resolve potential safety concerns about the subtherapeutic use of antibiotics in animal feed.[9] Section 135.109, the predecessor to 21 C.F.R. § 558.15, provided that FDA would revoke "currently approved" subtherapeutic uses of antibiotics, including bacitracin MD, unless data were submitted pursuant to an identified schedule. The proposed regulation identified those sponsors "eligible for interim marketing based on their compliance with the requirements" of the regulation. Importantly, S.B. Penick & Co. was the only drug sponsor for bacitracin MD listed in § 135.109.[10]

---

7 68 *Fed. Reg.* at 47273.

8 Pennfield has represented that its predecessors in interest for this product include Nopco, Diamond Shamrock Chemical Company, SDS Biotech Corporation, Fermenta Animal Health Co., and Boehringer Ingelheim Vetmedica, Inc. (BIVI). *See* Letter from Donald A. Gable, BIVI, to FDA (dated September 18, 1998) (obtained under FOIA) (copy enclosed as Attachment 1), at page 2. Alpharma does not challenge this corporate succession.

9 39 *Fed. Reg.* 28393 (August 6, 1974). This action followed Federal Register announcements of February 1, 1972 (37 *Fed. Reg.* 2444); April 20, 1973 (38 *Fed. Reg.* 9811); and September 5, 1973 (38 *Fed. Reg.* 23942).

10 39 *Fed. Reg.* at 28394. S.B. Penick & Co., A.L. Laboratories, Inc., and A.L. Pharma Inc. are predecessors in interest to Alpharma Inc.

On February 25, 1976, FDA promulgated the final version of 21 C.F.R. §558.15. The order identified "the drug firms and the antibacterial drugs intended for use in animal feeds which they sponsor that are currently in compliance with the provisions of §558.15."[11] Section 558.15(g)(1) provided an exclusive list of antibacterial drug premixes for which sponsors had filed commitments to conduct additional studies to conclusively resolve the safety issues of their subtherapeutic usage. In comment 17 of the rule, FDA noted that Diamond Shamrock Chemical Company (DSCC) had "questioned its omission from the list of approved sponsors in [proposed] § 558.15(g)(2)."[12] The response to the comment detailed that the Commissioner had reviewed the materials submitted by DSCC and concluded that the firm complied with the "intent and critical elements of § 558.15" and added DSCC to the sponsor list for antibacterial premixes for bacitracin MD in 21 C.F.R. §558.15(g)(1).

However, the record supporting this determination is scant at best. FDA documented its concerns with DSCC's inclusion and apparently "resolved" the matter in the following way:

> The question has arisen in the Bureau of Veterinary Medicine and the Office of General Counsel as to whether or not bacitracin products were marketed by Diamond Shamrock (D/S) prior to August 1, 1969. This question is important since products on the market prior to that time are covered by the "transitionally approved" provisions of the Act. Dr. McKenna, at my request, checked Company records on the marketing of bacitracin M.D. and zinc bacitracin. Dr. McKenna telephoned me back on the same day to report that both feed-grade and water soluble bacitracin M.D. and zinc bacitracin were marketed by D/S, in his words, "well before August 1, 1969."[13]

The assertion by a representative of DSCC appears to be the sum of the evidence presented to FDA that DSCC was eligible for interim marketing rights. On its face, the assertion does not establish that DSCC had a required prior approval. Dr. McKenna's comment may accurately describe a situation where DSCC merely served as a distributor of bacitracin MD manufactured by another party. As shown below, evidence available both at the time of the development of 21 C.F.R. § 558.15 and in subsequent actions overwhelmingly supports a conclusion that DSCC was not eligible. FDA's initial action omitting DSCC from the sponsor list was correct.

---

[11] 41 *Fed. Reg.* at 8282.

[12] *Id.* at 8287. Alpharma believes that the reference to § 558.15(g)(2) is an error and should read "(g)(1)."

[13] FDA Memorandum of telephone conversation between Joseph McKenna, DSCC, and Gerald B. Guest, DVM (dated November 5, 1975) (obtained under FOIA) (copy enclosed as Attachment 2).

C. Information Available to FDA During the Development of 21 C.F.R. § 558.15 Supports the Conclusion that DSCC Did Not Have an "Approved" Product

The National Academy of Sciences/National Research Council's (NAS/NRC) evaluation of bacitracin formulations under the DESI program did not include a product owned by any of Pennfield's predecessors in interest, including DSCC. The list of products reviewed by NAS/NRC was a reflection of the new animal drugs using bacitracin, with or without penicillin, approved between 1938 and 1962. FDA evaluated the products for which NAS/NRC provided reports as "probably effective for the growth claims in poultry and probably not effective for the growth claim in swine or for the therapeutic claims." A bacitracin formulation from DSCC was not listed among reports reviewed by FDA as part of report 0061NV.[14] FDA published an announcement not only to inform the subject products' manufacturers of the findings but also to inform all interested parties that such articles must be the subject of an approved NADA in order to be marketed and must comply with the FDC Act. FDA gave manufacturers of the subject drugs, and presumably other interested parties, 6 months from the report publication date to submit adequate documentation in support of the labeling used on the product.

Following publication of the proposal in August 1974, FDA noted that there were substantial printing errors in the August 6 tables and provided a corrected version of the information.[15] The "printing errors" apparently did not include any new-found realization that DSCC or a related company in fact held an approval for bacitracin MD. Rather, S.B. Penick remained the only drug sponsor listed for this animal drug.

Most importantly, DSCC's written objection in 1974 did not assert that the company had approval for a bacitracin MD product. Rather, the company claimed that it was "an active member of the cooperative group in support of the" long-term safety studies being conducted on bacitracin MD.[16] However, simply participating in the studies themselves did not entitle a party to the "interim marketing" rights otherwise confirmed by 21 C.F.R. § 558.15. As noted above, "only drugs and sponsors which the Commissioner has determined to be approved for use by NADA, NDA, master file, antibiotic regulation, or food additive regulation" were to be listed in the regulation.[17] DSCC's 1974 letter included two attachments with respect to bacitracin MD, but none of this information predated October 1973. Thus, even at the time 21 C.F.R. § 558.15(g) was being developed, DSCC offered no evidence to support its claim to an approval for a bacitracin MD product.

---

14 35 *Fed. Reg.* 11531 (July 17, 1970).

15 39 *Fed. Reg.* 34682 (September 27, 1974).

16 Letter from DSCC to FDA Hearing Clerk (dated September 18, 1974) (with attachments) (obtained under FOIA) (copy enclosed as Attachment 3).

17 41 *Fed. Reg.* at 8285 (FDA response to comment 6).

D. FDA Action in the Early 1980s Reaffirmed FDA's Position That Diamond Shamrock Chemical Company Did Not Have Approval for Bacitracin MD

In 1981, FDA took preliminary steps to begin finalizing the NAS/NRC review of bacitracin premixes and soluble powder. To this end, FDA sent letters to both A.L. Laboratories and International Mineral and Chemical Corp. (IMC) regarding the NAS/NRC review. FDA indicated that, "[i]n the case of bacitracin premixes and soluble powder, there are only two sponsors, [A.L. Laboratories] and International Mineral and Chemical Corp., holding approval for similar products" (emphasis added).[18] Based on the NADA numbers identified in the letter, FDA's letter addressed both bacitracin MD and bacitracin zinc (another antibiotic animal feed ingredient). The letter indicates that FDA considered A.L. Laboratories and IMC as the only two holders of approval for bacitracin premixes and soluble powder subject to NAS/NRC finalization. Despite FDA's listing of DSCC in the February 25, 1976 Federal Register, the 1981 letter did not identify DSCC or any successors as a holder of such an approval. If the 1976 conclusion was correct, FDA's records should have supported this position only five years later.

In 1982, FDA published a final rule withdrawing approval of those claims that were NAS/NRC reviewed and found probably not effective or which were not otherwise supported by adequate and well-controlled studies.[19] During this finalization procedure, FDA provided no indication that it was aware of any additional bacitracin MD products on the market.

E. FDA Action in the Mid 1990s Provides Additional Support for the Conclusion that the Available Evidence Does Not Support Existence of a DSCC Approval

FDA relayed its skepticism as to the basis of Fermenta Animal Health Company's (Fermenta) (a successor to DSCC) claimed approval for a Bacitracin MD Type A Medicated Article in 1996. The Agency noted that Fermenta's product was identified in 21 C.F.R. § 558.15, but also stated that "[b]ased on a review of the available files, [FDA] was not able to establish that your product has ever been approved either by a form 6 or otherwise" (emphasis added).[20] Since an existing approval was a prerequisite to listing in § 558.15, the statement by FDA that Fermenta's product did not have approval demonstrates the product should not have been included and that Fermenta (Pennfield's predecessor) did not enjoy the interim marketing rights associated with listing.

---

[18] Letter from Lonnie W. Luther, Chief, Metabolic Products Branch to A.L. Laboratories, Inc. (dated August 4, 1981) (copy enclosed as Attachment 4), at page 1.

[19] 47 *Fed. Reg.* 42100 (September 24, 1982).

[20] Letter from Andrew J. Beaulieu, Deputy Director, Therapeutic & Production Drug Review, Office of New Animal Drug Evaluation to Fermenta Animal Health Company (dated June 13, 1996) (obtained under FOIA) (copy enclosed as Attachment 5), at page 1.

Boehringer Ingelheim Vetmedica, Inc. (BIVI), Fermenta's direct successor, expressed uncertainty about its approval status to FDA in July 1998. In a surprising request for a company that supposedly had long-existing approval, BIVI sought FDA's help in confirming the most important aspect of any such approval – the claims. BIVI 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?[21]

FDA reiterated its concerns about BIVI's approval status shortly after BIVI's letter to the Agency dated July 16, 1998. FDA explained that the preamble to 21 C.F.R. § 558.15 permitted only new animal drugs determined to be approved for use by the mechanisms previously discussed were appropriate for listing and eligible for the interim marketing rights. FDA asserted that it had attempted to reconstruct records of approval for BIVI's product and discovered the Agency's records were incomplete. "The Agency has been unable to reconstruct from its records the existence of an approval for the product ... represented by the following listings for [BIVI] in section 558.15: Bacitracin methylene Disalicylate . . ." (emphasis added).[22] FDA had previously stated publicly that "many such approvals were issued long ago, and some may never have been used by the holder of the approval. Consequently, the current files of ... FDA may be incomplete and may fail to reflect the existence of some approvals."[23] However, not having proof of an approval may indicate something more than FDA's poorly maintained files; it may also be that an approval had never been granted for the product.

FDA notified BIVI that it wanted to "confirm existence of the approval status of new animal drugs for the conditions of use listed in § 558.15." Given the absence of approval records within the Agency's files, it invited regulated parties to submit evidence of their earlier approvals. FDA's letter asked that:

> sponsors, if they have information (including statements from persons with personal knowledge) establishing that an approval was granted prior to February 25, 1976, . . . identify the involved product(s) and certify the approval status to the Agency. . . . The Agency will use the certification you provide along with the statement in the preamble to 21 C.F.R. § 558.15 and other information in the Agency's files regarding the approval status of the new animal drug as the administrative record of the approval.[24]

---

[21] Letter from Donald A. Gable, BIVI, to FDA (dated July 16, 1998) (obtained under FOIA) (copy enclosed as Attachment 6), at page 3.

[22] Letter from Stephen F. Sundlof, Director of Center for Veterinary Medicine, to BIVI (dated July 29, 1998) (obtained under FOIA) (copy enclosed as Attachment 7), at page 2.

[23] 42 *Fed. Reg.* 423772 (August 30, 1977); 42 *Fed. Reg.* 56264 (October 21, 1977).

[24] Letter from Stephen F. Sundlof (dated July 29, 1998) (Attachment 7), at page 2.

The BIVI representative responded that "[w]hile I cannot offer certification, it is the knowledgeable opinion of the undersigned that FDA probably approved one or more Antibiotic Form 6s for NOPCOs bacitracin containing premixes" (underlining added).[25] However, the letter in response to FDA's request goes further to point out that "this opinion appears to be mute [sic] based upon the certification specifications" requested by FDA. BIVI was unwilling to make the required certification as to the approval status of the bacitracin MD product at that time.

BIVI's subsequent correspondence of September 18, 1998, included an "extensive history" that traced the product back to March 14, 1974. A comment in the history noted that the "critical element identified in the Federal Register was participation in 21 CFR 558.15 safety studies, not the existence of an approved Form 4 or Form 6 for Diamond Shamrock Chemical Company's bacitracin MD (NOPTRACIN® MD-50)."[26] As noted above, this assertion is only partially correct and misses a fundamental point: only those sponsors of products approved before the Animal Drug Amendments of 1968 took effect were eligible for inclusion in 21 C.F.R. § 558.15, based on a commitment to perform additional studies. The commitment itself is not determinative.

Subsequent correspondence from BIVI to FDA in November 1998 regarding the bacitracin MD product highlights the fact that the approval cannot be substantiated. For example, BIVI's representative asserted: "Further, I truly believe that NOPTRACIN® MD-50 Type A Medicated Article was approved as the subject of an Antibiotic Form 6 with the NOPCO CHEMICAL COMPANY as the sponsor (date of approval not known, but probably in the 1960s)" (underlining added).[27] In effect, BIVI guessed that it must have approval, but it had no evidence. FDA cannot support an important regulatory decision with nothing more than supposition. A "belief" that a product was approved is not a basis for receiving the interim marketing rights established by Section 108 of the Animal Drug Amendments of 1968.

F. The NOOH and Other Recent Actions Confirm the Lack of Evidence of Pennfield's Approval

The NOOH published on August 8, 2003, contains further information questioning the approval status of Pennfield's bacitracin MD.[28] FDA stated that there were "several sources of confusion as to NADA 141-137 and its interim status." In particular, FDA indicated that its

---

[25] Letter from Donald A. Gable, BIVI, to FDA (dated September 18, 1998) (Attachment 1), at page 4.

[26] Letter from Donald A. Gable, Fermenta, to Center for Veterinary Medicine (dated June 22, 1995) (obtained under FOIA) (copy enclosed as Attachment 8), at page 2.

[27] Letter from Donald A. Gable, BIVI, to Center for Veterinary Medicine (dated November 17, 1998) (obtained under FOIA) (copy enclosed as Attachment 9), at page 1.

[28] 68 *Fed. Reg.* at 47332.

administrative records were incomplete as to Pennfield's NADA 141-137, "calling into question its approval status."[29] The BIVI responses discussed above included a label dated February 1969 and a statement regarding its consistency with the claims permitted by 21 C.F.R. § 558.15.[30] However, the label does not provide strong evidence that DSCC had approval. While it may indicate that a product was on the market, the label may be equally interpreted as demonstrating that DSCC was merely distributing a product manufactured for it. In light of the numerous, repeated statements over many years clearly establishing that such an approval cannot be documented, the significance and provenance of this label is questionable.

FDA has no record of any approval for DSCC and the successor companies have not been able to supply evidence that satisfactorily demonstrates approval before August 1, 1969. In fact, the only support for a timely DSCC approval is FDA's comment in the 1976 final rule (in which it simply deferred to a company "certification" that it had been granted approval). However, the Agency's initial conclusion (omitting DSCC), plus all of the subsequent information discussed above, show that the 1976 decision was incorrect.

G. The Listing of DSCC's Bacitracin MD in 21 C.F.R. § 558.15 in 1976 was an Improper Action

As discussed in the preceding sections, it is clear from the record that, at best, FDA relied on an unsubstantiated oral representation from DSCC that it was marketing bacitracin MD before August 1, 1969. This self-serving assertion, by itself, does not establish the existence of the prior product approval needed for a sponsor to be listed in 21 C.F.R. § 558.15. The record in 1976, like today, contains absolutely nothing of substance to support the contention that DSCC had approval for bacitracin MD prior to August 1, 1969.

1. Section 558.15 Could Only Reflect Already-Existing Interim Marketing Rights, Not Create Them Anew

Between the 1968 Amendments and the Generic Animal Drug and Patent Term Restoration Act of 1988, the only way to obtain approval of a new animal drug for non-DESI claims was to submit a new animal drug application (NADA) including full studies demonstrating safety and effectiveness. It is clear that animal drugs must be approved before being marketed and in order to gain approval the manufacturer must demonstrate safety and effectiveness.

---

29 68 *Fed. Reg.* at 47334.

30 February 1969 label (obtained under FOIA) (copy enclosed as Attachment 10); Letter from Donald A. Gable, BIVI, to FDA (dated September 18, 1998) (Attachment 1), at page 4. There is no evidence that DSCC submitted this label as part of the administrative proceedings when the list of sponsors in 21 C.F.R. § 558.15 was being developed in the early 1970s.

Under the Administrative Procedure Act (APA), agency action, findings, and conclusions will be held unlawful and set aside if found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."[31] FDA's authority to promulgate 21 C.F.R. § 558.15 stems from FDC Act §§ 512 and 701(a).[32] While Section 701(a) bestows upon FDA general rulemaking authority for the efficient enforcement of the FDC Act, that authority does not allow FDA to amend the statute or promulgate rules that are beyond the statutory grant of authority.[33] Agency actions that do not fall within the scope of statutory delegation of authority are *ultra vires* and must be invalidated by reviewing courts.[34] The 1968 Amendments extended interim marketing rights only to companies that already had approval. Therefore, the question of whether Pennfield or its predecessors now have interim marketing rights was then and has ever been a matter of fact. Did a Pennfield predecessor have approval as of August 1, 1969 or not? In the absence of suitable evidence of the fact of prior approval, FDA may not create an approval other than by the statutorily mandated process described in Section 512 of the FDC Act.

In 1976, the Commissioner incorrectly concluded that DSCC's product had been granted approval; there was insufficient evidence to reach such a conclusion.[35] The Commissioner arguably had the authority to compile a list of sponsors who would be eligible for interim marketing status if they made a commitment to conduct additional safety studies. However, he certainly did not have the authority to grant interim marketing rights to those sponsors who were committed to performing additional safety studies but whose products had not been approved before the Animal Drug Amendments of 1968 took effect. The purpose of the § 558.15 list was to give sponsors who had already received approval the ability to maintain their interim marketing status by participating in safety and efficacy studies. It was not intended to, and legally could not, grant interim marketing status to those sponsors who only committed to conduct additional studies but who did not have a prior approved product. Therefore, since the record is devoid of evidence showing an existing approval, DSCC was improperly added to the list in 21 C.F.R. § 558.15(g)(1).

2. Agency Action Must be Supported by an Adequate Record

As discussed above, whether or not DSCC had prior approval is a question of fact. FDA's amendment of the § 558.15(g)(1) list to include DSCC merely created an illusion of interim marketing rights that could not withstand judicial review because FDA did not base its conclusion that such rights existed on any relevant and material facts. In the past, inadequate

---

31 5 U.S.C. § 706(2)(C).

32 21 U.S.C. §§ 360b, 371(a).

33 *See American Public Health Assn. v. Veneman*, 349 F.Supp. 1311 (D.D.C. 1972); *see also Hoffman La Roche v. Weinberger*, 425 F.Supp. 890 (D.D.C. 1975).

34 *See Haitian Centers Council, Inc. v. Sale*, 823 F.Supp. 1028 (E.D.N.Y. 1993).

35 41 *Fed. Reg.* at 8287.

records have led to judicial disapproval and remand of the agency action.[36] A rule promulgated on the basis of inadequate data "is not consonant with the purpose of the rulemaking proceeding."[37] In this case, the error must be corrected by acknowledging that Pennfield's predecessors never had interim marketing rights for bacitracin MD.

FDA failed to properly establish that DSCC's bacitracin MD was approved before adding it to the list of parties eligible for interim marketing rights in 21 C.F.R. § 558.15(g)(1). It is an agency's responsibility to maintain detailed records in order to show that its decisions are based on logical reasoning. This duty keeps the agency accountable for its acts and gives injured parties a basis upon which to challenge the agency's decisions. A concrete record also gives the agency the ability to defend challenges. There was no evidence to support FDA's decision to add DSCC in 1976, and extensive documentation confirms that such evidence does not exist now. As a consequence, Pennfield is not now, and never has been, eligible for interim marketing status.

FDA's initial list of companies with interim marketing rights presumably was compiled after the Agency had conducted an extensive review of its records of drugs that had existing approvals and sponsors who had committed to conducting the required studies. Based on these contemporaneous findings, FDA did not identify DSCC as a party with an existing approval.[38] The NAS/NRC evaluation of bacitracin formulations under the DESI program did not include a product owned by DSCC or any of Pennfield's other predecessors.[39]

DSCC's objection in 1974 committed to conducting additional safety studies but failed to assert that approval had been granted prior to August 1, 1969.[40] The attachments submitted by DSCC did not even contain information pre-dating 1973. FDA apparently "resolved" this matter on the basis of a single telephone call, with no further documentation submitted.[41] However, at the time 21 C.F.R. § 558.15 was promulgated there was absolutely no evidence that DSCC was in possession of an approval. Indeed, even today there is no evidence that DSCC had a required

---

36 *See, e.g., Almay, Inc. v. Califano*, 569 F.2d 674 (D.C. Cir. 1977) (holding that the FDA's definition of "hypoallergenic" was arbitrary and capricious for lack of sufficient evidence, and its use of the flawed consumer survey was a clear error of judgment); *see also United States v. Nova Scotia,* 568 F.2d 240 (2d Cir. 1977) (holding that a regulation over the processing of whitefish was invalid because the agency record failed to disclose the basis of the regulation, therefore interfering with the comment process).

37 *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 393 (1973).

38 39 *Fed. Reg.* at 28394.

39 35 *Fed. Reg.* at 11531.

40 Letter from DSCC to FDA Hearing Clerk (dated September 18, 1974) (with attachments) (Attachment 3).

41 FDA Memorandum of telephone conversation (dated November 5, 1975) (Attachment 2).

approval for bacitracin MD at the time the regulation was developed. FDA's decision to add DSCC to the § 558.15 list was unsupported then and is unsupportable now.

FDA has even admitted that the evidence is scant at best and insufficient to support its decision. In 1996, after reviewing the available files, FDA wrote a letter to Pennfield's predecessor and stated that it was "not able to establish that your [bacitracin MD] product has ever been approved."[42] In 1998, FDA stated that it was "unable to reconstruct from its records the existence of an approval for a [bacitracin MD] product."[43] To cure the deficient record, FDA solicited the regulated party itself to provide information that the product had been approved. As a result, FDA's only basis for the belief that an approval had been granted is the representation made by one of Pennfield's predecessors that the application was "probably approved"[44] but "date of approval [is] not known."[45] This record simply does not support the Agency's decision to recognize interim marketing rights for Pennfield or its predecessors because there is no evidence that approval for the bacitracin MD product was ever granted.

H. CONCLUSION – Pennfield Is Not Now and Never Has Been Eligible for "Interim Marketing Rights" for Bacitracin MD

Given the utter lack of evidence, FDA does not have an appropriate basis to conclude that DSCC's bacitracin MD product was ever granted approval. Consequently, DSCC's successors in interest are not now and have never been eligible for the interim marketing rights associated with listing in 21 C.F.R. § 558.15. Not only does FDA's record lack a copy of any such approval, but the Agency has also continually questioned the status of the product with a series of owners. Not one of these companies – NOPCO, DSCC, SDS Biotech Corporation, Fermenta, BIVI, or Pennfield – has been able to adequately satisfy FDA's queries about the product's underlying approval. The best that any company has offered is merely speculation that the product was "probably approved." As discussed above, product approval by a NADA, NDA, master file, antibiotic regulation, or food additive petition was necessary for interim marketing rights to arise, regardless of whether the company listings in 21 C.F.R. § 558.15 were valid.

The overall lack of file maintenance by FDA has contributed to the confusion associated with this product. However, poor file management is not the root of the problem. Rather, the reason no approval is on file with FDA is that there is no approval to be documented. FDA has stated as much in its actions in 1974 and in the correspondence with DSCC and its successors over the intervening decades.

---

42 Letter from Andrew Beaulieu (dated June 13, 1996) (Attachment 5), at page 1.

43 Letter from Stephen F. Sundlof (dated July 29 1998) (Attachment 7), at page 2.

44 Letter from Donald A. Gable (dated September 18, 1998) (Attachment 1), at page 4.

45 Letter from Donald A. Gable (dated November 17, 1998) (Attachment 9), at page 1.

As a result, Pennfield's NADA 141-137 is not now and has never been eligible for the "interim marketing" rights provided by 21 C.F.R. § 558.15. Under these circumstances, FDA must conclude that Pennfield is ineligible to market any bacitracin MD products, even for the DESI claims found to be effective in the NOOH document.

ENVIRONMENTAL IMPACT

This Petition claims a categorical exclusion under 21 C.F.R. §25.33.

ECONOMIC IMPACT

This information will be provided if requested by the Commissioner.

CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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

Attachments:

1. Letter from Donald A. Gable, BIVI, to FDA (dated September 18, 1998)
2. FDA Memorandum of telephone conversation between Joseph McKenna, DSCC, and Gerald B. Guest, DVM (dated November 5, 1975)
3. Letter from DSCC to FDA Hearing Clerk (dated September 18, 1974) (with attachments)
4. Letter from Lonnie W. Luther, Chief, Metabolic Products Branch to A.L. Laboratories, Inc. (dated August 4, 1981)
5. Letter from Andrew J. Beaulieu, Deputy Director, Therapeutic & Production Drug Review, Office of New Animal Drug Evaluation to Fermenta Animal Health Company (dated June 13, 1996)
6. Letter from Donald A. Gable, BIVI, to FDA (dated July 16, 1998)
7. Letter from Stephen F. Sundlof, Director of Center for Veterinary Medicine, to Boehringer Ingelheim Vetmedica, Inc. (dated July 29, 1998)
8. Letter from Donald A. Gable, Fermenta Animal Health, to Center for Veterinary Medicine (dated June 22, 1995)
9. Letter from Donald A. Gable, Boehringer Ingelheim Vetmedica, Inc., to Center for Veterinary Medicine (dated November 17, 1968)
10. February 1969 bacitracin MD label