

to the current sponsors, which are Alpharma, Inc., and Pennfield Oil Co., respectively.

A second, more complicated example involves BMD's approved conditions of use. Rather than listing the use levels and indications for use for which interim marketing is permitted, the table in § 558.15(g)(1) contains a reference to another section of the regulations. When the table was first published in 1976, this reference was to the uses and indications listed in 21 CFR 121.225 and 121.252 (see 41 FR 8282, February 25, 1976). These were the conditions of use for which the BMD products were approved, under the transitional approval provisions of the Animal Drug Amendments of 1968. Shortly thereafter, these uses were recodified in § 558.76 and the reference in § 558.15(g)(1) was adjusted accordingly (41 FR 10984, March 15, 1976). Since that recodification, § 558.76 has been amended numerous times to reflect the approval of supplemental applications, based on proprietary data, that were filed by sponsors other than Pennfield Oil Co. or its predecessors in interest (see, e.g., 63 FR 40824, July 31, 1998). At the time of these amendments to § 558.76, the table in § 558.15(g)(1) was not updated by removing the simple cross reference to § 558.76 and by adding in its place a correct reference or a correct listing of the uses for which interim marketing was permitted. Thus, the table is misleading unless the reader already knows the indications for which the sponsors are approved or reviews the changes made over time to §§ 558.15 and 558.76.

The confusion caused by the reference in § 558.15(g)(1) to the use levels and indications for use in § 558.76 is illustrated by, and perhaps exacerbated by, the administrative record for NADA 141-137. As happened with several other products listed in § 558.15, it became apparent in the 1990s that the administrative record for this NADA was incomplete, calling into question its approval status. This is described in more detail in the proposed rule to remove § 558.15 published elsewhere in this issue of the **Federal Register**. In 1998, to help resolve the approval status, the company that owned the product at the time, Boehringer Ingelheim Vetmedica, Inc. (BIVI), certified that the product was approved pre-1968 and provided supporting information. This certification was made by a letter dated September 18, 1998, as amended by a letter dated November 17, 1998. It provided historical information about the product, stated that the product had

been approved prior to 1968, and stated that it was subject to the transitional approval provisions of the Animal Drug Amendments of 1968. The company also provided information about the approved indications. One piece of information, included with the September letter, is a product label dated February 1969. BIVI stated that this label is consistent with § 558.15. This was probably intended to mean the interim marketing table in § 558.15 as it was originally issued in 1976 since the label's indications are generally consistent with, albeit somewhat narrower than, BMD's indications listed in the table at the time. Given this consistency and given that the date of the label is just a few months before the effective date of the transitional approval provision, the label provides good evidence that the product was subject to transitional approval and the indications for which it was transitionally approved.

However, two other pieces of information appear to be inconsistent with the indications for which FDA believes Pennfield Oil Co.'s BMD product is transitionally approved. The November 1998 letter from BIVI states that the product was approved for "the indications for use itemized in 21 CFR § 558.78," which was presumably meant to be § 558.76 since the other regulation (§ 558.78) concerns bacitracin zinc. It is unclear whether BIVI meant the indications in § 558.76 in 1976 or 1998. Also unclear is the meaning of two labels faxed by BIVI to FDA on December 9, 1998. These are in the product's current NADA file, although without any cover page or other explanatory notes. These labels, one a subset of the other, specify indications that are much closer to those listed in § 558.76 in 1998 than to those that were transitionally-approved. It is possible that the labels BIVI faxed to FDA on December 9, 1998, were based on § 558.76 as it existed at that time, given that the BMD listing in § 558.15 contained the misleading cross-reference to § 558.76.

On December 17, 1998, FDA sent BIVI a letter stating that the agency received the company's November certification that amended the September letter, that the certification would be used as part of the administrative record of approval, and that the agency planned to codify this approval as soon as possible given resource constraints and public health priorities. FDA's letter also referred to the indications "specified in the labeling attached to [BIVI's] letter." However, FDA's letter does not state to which labeling it is referring.

We are not aware of any additional approved indications beyond those listed in the original § 558.76 from 1976 for Pennfield Oil Co.'s product. If the sponsor has additional information on the other approved indications, such information should be provided to FDA during this administrative process.

B. Oxytetracycline and Neomycin Fixed-Combination Type A Medicated Articles

The agency is making findings of effectiveness for oxytetracycline and neomycin fixed-combination Type A medicated articles for use in animal feed. These findings cover the following drugs:

- NADA 94-975, NEO-TERRAMYCIN (oxytetracycline and neomycin). Phibro Animal Health, 710 Route 46 East, suite 401, Fairfield, NJ 07004.

- NADA 138-939, NEO-OXY (oxytetracycline and neomycin). Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137.

Both of these products are two-way, fixed-combination Type A medicated articles used to make two-way combination drug Type C medicated feeds at use levels for the species and indications listed in § 558.15(g)(2). The drug sponsor information in this listing is outdated, however, designating Pfizer, Inc., Pennfield Oil Co., and VPO, Inc., instead of Phibro Animal Health and Pennfield Oil Co.

The National Academy of Sciences/National Research Council (NAS/NRC) assisted FDA in its DESI program for numerous animal drug products. While NAS/NRC did not evaluate the efficacy data relating to these combinations, FDA has conducted such a review. This review was based on the agency's findings of effectiveness for oxytetracycline and neomycin single-ingredient feed use products, which in turn were based on NAS/NRC's evaluation (see 35 FR 7089, May 5, 1970, and 36 FR 837, January 19, 1971). FDA has determined that its previous findings of effectiveness for the single ingredients are applicable to the combinations in the absence of information indicating interference in effectiveness between individual ingredients. The agency's review also considered information about the effectiveness submitted to these two NADAs, although this information did not alter the agency's conclusions based on the single-ingredient findings. Tables 2, 3, 4, and 5 of this document summarize FDA's findings of effectiveness for oxytetracycline and neomycin fixed-combination Type A medicated articles for use in animal feed.