DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. 2003N–0324]

New Animal Drugs; Removal of Obsolete and Redundant Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing regulations that exempted certain new animal drugs administered in feed from batch certification requirements. FDA is also removing portions of a regulation that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofuran, and sulfonamide drugs administered in animal feed. The intended effect of this rule is to remove regulations that are obsolete or redundant. The portions of the latter regulation that are being removed are most of the Type A medicated articles and use combinations that are listed in the tables contained in that regulation. This rule does not finalize the provisions of the proposed rule regarding removing the remainder of that regulation.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**].

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 2003 (68 FR 47272), FDA published a proposed rule to remove and reserve 21 CFR 510 Subpart F—*Animal Use Exemptions From Certification and Labeling Requirements* (part 510), consisting of § 510.515 *Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act* (§ 510.515), and 21 CFR 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (§ 558.15) on the grounds that these regulations were obsolete or redundant.

The proposed rule explained the nature and purpose of §§ 510.515 and 558.15. It also explained that most of the products and use combinations subject to the listings in § 558.15 had approvals that were already codified in part 558 subpart B. It described three categories of products and use combinations subject to the listings in § 558.15 that did not have approvals codified in part 558 subpart B.

The first category consisted of nine products and use combinations that were approved but which were subject to the Drug Efficacy Study Implementation (DESI) program. In the same issue of the **Federal Register** as the proposed rule, FDA published a notice of opportunity for hearing (NOOH), which announced the agency's findings of effectiveness for these products and use combinations (68 FR 47333). The agency proposed to withdraw the new animal drug applications (NADAs) for those products and use combinations lacking substantial evidence of effectiveness, following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the agency provided an opportunity for hearing. In response to the NOOH, FDA received supplemental applications for seven of the products and use combinations

with labeling conforming to the relevant findings of effectiveness. FDA has approved those applications and, elsewhere in this issue of the **Federal Register**, FDA is publishing final rules amending part 558 subpart B to reflect those approvals. FDA received hearing requests for the other two products.

In the second category was one use combination that was approved but was not subject to the agency's DESI program. In the same issue of the **Federal Register** as the proposed rule, FDA issued a final rule amending part 558 subpart B to reflect this approval (68 FR 47237).

The third category contained five use combinations the agency believed were not approved and, therefore, were erroneously listed in § 558.15. The proposed rule stated that the agency was unaware of any company that currently marketed any of these use combinations, and requested that if a company wished to market one of them then it should present evidence supporting approval to avoid facing potential regulatory action in the event of future marketing. To date, no company has asserted that it holds a valid approval for them.

II. Comments on the Proposed Rule and Summary of the Final Rule

The agency received only one set of comments on the proposed rule, from Pennfield Oil Co. (Pennfield). Pennfield owns a bacitracin methylene disalicylate (BMD) Type A medicated article, NADA 141–137, that is listed in the table in § 558.15(g)(1). This listing is under Fermenta Animal Health Co., which is a predecessor in interest to Pennfield. Pennfield also owns an oxytetracycline/neomycin Type A medicated article, NADA 138–939, that is listed in the table in § 558.15(g)(2). In response to the NOOH, FDA received hearing requests regarding both of these products.

A. Removal of § 510.515

The comment agreed with the agency's position that § 510.515 is obsolete and stated that it did not oppose the removal of this provision. Thus, there were no opposing comments and, for the reasons described in the proposed rule, FDA is removing part 510 subpart F. FDA is also making a conforming change in § 558.4 *Requirement of a medicated feed mill license*.

B. Removal of § 558.15

The comment objected to removal of § 558.15 until the issues in the NOOH are addressed. It argued that the BMD listing in § 558.15 provides evidence of Pennfield's approval and that removal of that section, without updating the BMD listing in part 558 subpart B, would result in a lack of recognition in the regulations of the approval that Pennfield currently has.

FDA agrees that it should, at this time, maintain the listing for Pennfield's BMD Type A medicated article in § 558.15.

FDA is aware of only two approved new animal drugs for use in animal feeds that are not listed in part 558 subpart B—Pennfield's BMD and oxytetracycline/neomycin Type A medicated articles. FDA has decided to maintain both of these listings in § 558.15 until, as part of the DESI program, either their approvals are withdrawn or part 558 subpart B has been amended to reflect their approvals.

Thus, FDA is removing from the tables in § 558.15(g) those products and use combinations that are not approved and those products and use combinations whose approval is reflected in part 558 subpart B. FDA is retaining only the listings for NADA 141–137 and NADA 138–939 in those tables. In addition, FDA is retaining § 558.15(a) through (f) until all of the table listings are removed. FDA intends to finalize the proposed rule to remove all

of § 558.15 once, as part of the DESI program, either the approvals for NADA 141–137 and NADA 138–939 are withdrawn or part 558 subpart B has been amended to reflect their approvals.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–602), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not an economically significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

FDA proposed the removal of §§ 510.515 and 558.15 on August 8, 2003, because they were obsolete or redundant. The purpose of § 510.515 was to provide exemption from certification and labeling requirements of certain drugs used in animal feeds. FDA had discontinued the practice of certifying antibiotic animal drugs, thereby rendering the regulation obsolete relative to its intended purpose. The original purpose of § 558.15, requiring the submission of the results of studies on the long-term administration of then-

marketed antimicrobial drugs in animal feed on the occurrence of multiple drug-resistant bacteria associated with these animals, was also obsolete as FDA had a new strategy and concept for assessing the safety of antimicrobial new animal drugs, including subtherapeutic use of antimicrobials in animal feed, with regard to their microbiological effects on bacteria of human health concern.

A. Benefits

Only one set of comments to the proposal was received by FDA. Because these comments did not question the benefits as described in the proposed rule, we retain the benefits for the final rule. This final rule is expected to provide greater clarity in the regulations for new animal drugs for use in animal feeds by deleting obsolete provisions in §§ 510.515 and 558.15. We do not expect this final rule to result in any direct human or animal health benefit. Rather, this final rule would remove regulations that are no longer necessary.

B. Compliance Costs

The analysis of the proposed rule concluded that five combination uses would lose marketing ability as a result of the revocation of § 558.15, and that our previous attempts to contact the three sponsors of these five drug combinations led us to conclude that these sponsors no longer market these combinations. This conclusion is reinforced now by the lack of public comments on these five drug combination uses. Therefore, we do not expect the final rule that revokes § 558.15 to have a substantive effect on any approved new animal drugs, or to cause any approved new animal drug to lose its marketing ability or experience a loss of sales.

C. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact on a substantial number of small entities. FDA has determined that this final rule does not impose compliance costs on the sponsors of any products that are currently marketed. Further, it does not cause any drugs that are currently marketed to lose their marketing ability. We therefore certify that this final rule would not have a significant economic effect on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (as amended).

D. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the implicit price deflator for the gross domestic product. FDA does not expect this final rule to result in any 1 year expenditure that would meet or exceed this amount. As such, no further analysis of anticipated costs and benefits is required by the Unfunded Mandates Reform Act.

V. Paperwork Reduction Act of 1995

FDA concludes that this rule does not have information collection requirements.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

Subpart F [Removed and Reserved]

■ 2. Subpart F, consisting of § 510.515, is removed and reserved.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.4 [Amended]

■ 4. In paragraph (c) of § 558.4, remove ''§§ 510.515 and 558.15'' and add in its place ''§ 558.15''.

§ 558.15 [Amended]

■ 5. Amend § 558.15 as follows:

a. In the table in paragraph (g)(1), remove the entries for ''Pitman-Moore, Inc.'', ''A. L. Laboratories, Inc'', ''Elanco Products Co'', ''Sanofi Animal Health,

Inc.'', ''The Upjohn Co'', ''Pfizer, Inc'', ''Hoechst-Roussel Agri-Vet, Inc'', ''American Cyanamid Co., Fermenta Animal Health Co., Feed Specialties Co., Inc., Pfizer, Inc., PennField Oil Co., and VPO, Inc..'', ''Merck Sharp & Dohme Research Labs., and Solvay Veterinary, Inc.'', ''Pfizer, Inc., PennField Oil Co.'', ''American Cyanamid Co'', ''Hoffman-La Roche, Inc'', ''Pfizer, Inc.'', ''American Cyanamid Co. and Pfizer, Inc.'', and ''Boehringer Ingelheim Vetmedica, Inc..''; and under the ''Drug Sponsor'' column revise the entry for ''A.L. Laboratories, Inc., Fermenta Animal Health Co.'', to read ''Fermenta Animal Health Co.''; and

b. In the table in paragraph (g)(2), remove the entries for ''Boehringer Ingelheim Vetmedica, Inc.'', ''American Cyanamid Co'', ''The Upjohn Co.'', ''Pitman-Moore, Inc.'', ''Merck Sharp & Dohme Research Labs.'', ''A. L. Laboratories, Inc.'', ''Whitmoyer Labs, Inc'', and ''Elanco Products Co.''; and

under the ''Drug sponsor'' column revise the entry for ''Pfizer, Inc., PennField Oil Co., and VPO, Inc.'' to read ''PennField Oil Co.''

Dated: March 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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