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.

[FR Doc. 06–3121 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for the veterinary prescription use of flunixin meglumine injectable solution for the control of inflammation in horses and cattle.

DATES: This rule is effective March 31, 2006.

FOR FURTHER INFORMATION CONTACT: Christopher Melluso, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *christopher.melluso@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–387 for the use of Flunixin Injectable Solution by veterinary

prescription for the control of inflammation in horses and cattle. Cross Vetpharm Group's Flunixin Injectable Solution is approved as a generic copy of Schering-Plough Animal Health's BANAMINE (flunixin) Solution, approved under NADA 101–479. The ANADA is approved as of March 2, 2006, and the regulations in 21 CFR 522.970 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.970 [Amended]

■ 2. Section 522.970 is amended in paragraphs (b)(2) and (e)(2)(iii) by removing ''and 059130'' and by adding in its place ''059130, and 061623''.

Dated: March 13, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–3118 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. 2003N–0324]

New Animal Drugs for Use in Animal Feeds; Bacitracin; Nitarsone; Zoalene

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of three supplemental new animal drug applications (NADAs) filed by Alpharma, Inc. Two of the supplemental NADAs provide for the use of approved, single-ingredient Type A medicated articles containing bacitracin methylene disalicylate and zoalene, with or without roxarsone, to formulate two-way or three-way combination drug Type C medicated feeds for replacement chickens. The third NADA provides for the use of bacitracin zinc and nitarsone single-ingredient Type A medicated articles for two-way combination Type C medicated feeds for growing turkeys. These approvals reflect FDA's effectiveness conclusions, which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

DATES: This rule is effective March 31, 2006.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–50), 7519 Standish Pl., Rockville, MD 20855, 240–276–9090, e-mail: *andrew.beaulieu@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47332), as corrected October 7, 2003 (68 FR 57911), as part of the Drug Efficacy Study Implementation (DESI) program CVM announced the effective conditions of use for several drug products and use combinations listed in 21 CFR 558.15. CVM proposed to withdraw the NADAs for those products or 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. Alpharma, Inc., One Executive Dr., Fort Lee, NJ 07024, filed supplements to three of its approved NADAs to revise the labeling of its products to comply with these findings of effectiveness.

Alpharma, Inc., filed a supplement to approved NADA 141–130 for use of bacitracin methylene disalicylate and zoalene Type A medicated articles to formulate two-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing BMD (bacitracin methylene disalicylate) at 4 to 50 grams per ton (g/ton) and ZOAMIX (zoalene) at 36.3 to 113.5 g/ton of feed in replacement chickens for increased rate of weight gain and improved feed efficiency; and for development of active immunity to coccidiosis.

Alpharma, Inc., also filed a supplement to approved NADA 141–131 for use of bacitracin methylene disalicylate, zoalene, and roxarsone single-ingredient Type A medicated articles to make three-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing BMD (bacitracin methylene disalicylate) at 4 to 50 g/ton, ZOAMIX (zoalene) at 36.3 to 113.5 g/ton, and 3–NITRO (roxarsone) at 22.7 to 45.4 g/ton of feed in replacement chickens for increased rate of weight gain and improved feed efficiency; for development of active immunity to coccidiosis; and for improved pigmentation.

Alpharma, Inc., also filed a supplement to approved NADA 141–132 for use of bacitracin zinc and nitarsone single-ingredient Type A medicated articles to make two-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing ALBAC (bacitracin zinc) at 4 to 50 g/ton and HISTOSTAT (nitarsone) at 170 g/ton (0.01875 percent) of feed in growing turkeys for increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of blackhead.

The DESI evaluation is concerned only with the effectiveness of the drug products and use combinations. Nothing in this document constitutes a bar to further proceedings with respect to questions of safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

Products that comply with FDA's findings of effectiveness are eligible for copying as described in the *Generic Animal Drug and Patent Term Restoration Act Policy Letter Eight*, August 21, 1991 (56 FR 41561). Accordingly, sponsors may now obtain approval of abbreviated NADAs for