Spares

(b) As of the effective date of this AD, no person shall install an artificial feel unit having part number D2727040000600, D2727040000651, D2727040000800, or D2727040000851 on any airplane.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directive 1999–075–128(B), dated February 24, 1999.

Issued in Renton, Washington, on July 20, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–19016 Filed 7–23–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 99N–2151]

RIN 0910–AB69

New Animal Drug Applications; Sheep as a Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to reclassify sheep as a minor species for all data collection purposes. This would allow sponsors of supplemental new animal drug applications (NADA's) to extrapolate human food safety data from a major species such as cattle to sheep. In particular, this will allow the extrapolation of the tolerances for residues of new animal drugs in cattle to sheep.

DATES: Written comments must be submitted by October 25, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Meg Oeller, Center For Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7581.

SUPPLEMENTARY INFORMATION:

I. Minor Use and Minor Species

Since 1983 (48 FR 1922, January 14, 1983 (hereinafter referred to as the January 1983 final rule)), FDA has permitted some flexibility in the means to meet the data requirements to support the approval of new animal drugs intended for ''minor uses'' and ''minor species.'' Specifically, these classifications permit data extrapolation from a major use or major species to support the safety and effectiveness of a new animal drug for a minor use or minor species. The requirements were codified in § 514.1(d) (21 CFR 514.1(d)) by the January 1983 final rule (effective February 14, 1983).

''Minor use'' is defined as use of new animal drugs in a minor animal species, or use of new animal drugs in any animal species for control of a disease that occurs infrequently or in limited geographic areas. ''Minor species'' are defined by exclusion as any species other than horses, cattle, swine, dogs, cats, chickens, and turkeys. Sheep are classified as a minor species for the purposes of target animal safety and effectiveness studies. However, they are considered a major species for the purpose of determining the human food safety of edible products.

II. The Minor Species Designation and Safety and Effectiveness

The current minor use regulations (§ 514.1(d)) do not negate or alter the legal requirement that sponsors must provide data from ''adequate and well-controlled investigations'' to show effectiveness and ''adequate tests by all methods reasonably applicable'' to demonstrate safety. The agency has guidance that lays out its interpretation of what data for minor use/minor species drugs will be sufficient to meet these legal standards (Ref. 1). The regulations permit data provided in support of a drug approved for use in a major species to be used in support of an approval for the same drug for use in a minor species where scientifically appropriate.

III. The Minor Species Designation and Human food safety

The preamble of the January 1983 final rule (48 FR 1922 at 1923) described the toxicology, residue evaluation, and analytical methodology standards that are components of the human food safety evaluation for minor use drugs. For minor species, sufficient toxicology and metabolism data must be available within the residue evaluation data package in the application, or by reference, to establish a tolerance for new animal drug residues in animal-derived food. The tolerance is a limit on the amount of drug residue in edible tissue, as measured by the approved analytical method, that will not render the edible tissue adulterated under section 402(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(2)(D)).

The agency may require the residue evaluation data package to contain additional information on metabolism beyond that used for the approval in major species, if available information raises human food safety concerns about the level or toxicity of metabolic transformation products in edible tissues of the minor target species. In addition, if the conditions of safe use of the product require withholding of animals from slaughter for a prescribed period of time following treatment, a regulatory analytical method will be necessary. The sponsor of the minor use application must then demonstrate that the approved analytical methodology is suitable for monitoring compliance with the approved conditions of use.

IV. The Status of Sheep

In the preamble of the January 1983 final rule, the agency set out the justification for the determination that sheep are a major species for human food safety purposes. The agency's concern centered on consumers in the United States who eat a large proportion of lamb and mutton in their diets. In its evaluations, FDA used data from consumers who had reported eating sheep products during the previous 2 weeks. Using these values, FDA calculated that those consumers eat 24 percent as much lamb as beef. The agency determined that this was enough to categorize sheep as a major species for human food safety purposes. The agency stated in the preamble that it would be willing to reevaluate this conclusion if new data became available.

V. The Evidence to Support a Change in the Designation of Sheep

New data have become available since publication of the January 1983 final rule. These data allow the agency to conclude that sheep should be a minor species with respect to all data requirements. The new data concern the similarity of drug metabolism between sheep and cattle rather than consumption levels. The agency now believes that the body of evidence concerning drug metabolism is more significant in determining the major/minor status of species than consumption data because it demonstrates the reliability of data extrapolated from a major species. C. R. Short (Ref. 2) reviewed a collection of studies demonstrating that cattle and sheep metabolize drugs similarly. He documented the similarity in both major and minor pathways of drug metabolism between cattle and sheep, and found no differences of a qualitative nature.

These findings are further supported by a comparison of products that have been approved for use in both cattle and sheep under the current regulations. If sheep were considered a minor species for human food safety, the tolerance approved in cattle would be applied to sheep. A tissue residue depletion study would be conducted in sheep to establish the withdrawal period. To evaluate the impact of such an extrapolation, the agency reviewed the codified tolerances for cattle and sheep for those products with existing approvals in both species.

In most cases, the codified tolerances for cattle and sheep already are the same (e.g., ceftiofur, 21 CFR 556.113; chlortetracycline, 21 CFR 556.150; levamisole hydrochloride, 21 CFR 556.350; neomycin, 21 CFR 556.430; oxytetracycline, 21 CFR 556.500; tetracycline, 21 CFR 556.720; and thiabendazole, 21 CFR 556.730).

In two instances, the codified tolerances for cattle and sheep are different: Albendazole, 21 CFR 556.34 and ivermectin, 21 CFR 556.344. In the case of albendazole, the tolerance in cattle is lower than the tolerance in sheep (i.e., 200 parts per billion (ppb) for cattle and 250 ppb in sheep). In this case, application of the cattle tolerance to sheep would result in a longer withdrawal time than the application of the approved sheep tolerance. For ivermectin, the currently approved cattle tolerance of 100 ppb is higher than the approved sheep tolerance of 30 ppb. However, the original tolerance for cattle was 15 ppb (51 FR 27021, July 29, 1986). Following the original approvals in cattle and sheep, a revised acceptable daily intake (ADI) was calculated for ivermectin based on additional toxicological data (59 FR 50829, October 6, 1994). However, the revised ADI was used only to support a revision in the cattle tolerance to 100 ppb. The sheep tolerance was not similarly revised and remained at 30 ppb. Thus, the sheep tolerance of 30 ppb should be compared to the cattle tolerance of 15 ppb. In this circumstance, application of the cattle tolerance to sheep would also result in a longer withdrawal time. Thus, codified tolerances for existing approvals for cattle and sheep demonstrate that extrapolation of the tolerance is scientifically justified.

VI. Proposed Action

The proposed rule would amend § 514.1(d)(1)(ii) to designate sheep as a minor species with respect to all data collection purposes under NADA's. The effect of the change would be to permit the extrapolation of the tolerance from other closely related species, such as cattle, to sheep.

VII. Environmental Impact

The designation of sheep as a minor species means that most new animal drugs to be used in sheep fall within a category of actions which FDA considers to not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment nor an environmental impact statement is required (40 CFR 1508.4). The categorical exclusion is in § 25.33(d)(4) (21 CFR 25.33(d)(4)) of FDA's environmental regulations. Categorical exclusion under § 25.33(d)(4) for drugs for minor species applies to those new animal drugs that have been previously approved for use in another or the same species when similar animal management practices are used in the minor species.

VIII. Analysis of Economic Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 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). The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities, if the rule may have a significant impact on a substantial number of small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an 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.

FDA concludes that this proposed rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA estimates that the proposed rule will not impose any compliance costs on the animal drug industry, but rather expects it to provide a small cost savings for any company submitting an NADA for an animal drug to be used on sheep. As a result, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order. FDA has further determined, as described in the following paragraph, that the proposed rule will not have a significant economic impact on a substantial number of small entities. Further, since this proposed rule makes no mandates on other government entities and is not expected to result in expenditures of $100 million in any one year, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

FDA is proposing to amend the new animal drug regulations to reclassify sheep as a minor species for all data collection purposes, thereby allowing extrapolation from major species data to be used in conjunction with a total residue depletion study in sheep to meet the human food safety data standard for NADA's. Currently, FDA considers sheep a minor species for the purpose of the data necessary to demonstrate animal safety and effectiveness only. It considers sheep a major species for the purpose of human food safety requirements. This division in the classifications for sheep was originally based on expectations of consumption levels of sheep, especially among certain consumer groups. Since the original classification was made, new data demonstrating the similarity of drug metabolism between ruminant species has become available. Since there are not significant differences in the metabolism of most drugs between ruminant species, FDA believes most data packages supporting an NADA for use in sheep should be able to rely on the tolerance calculated for cattle.

The benefit of this proposed rule would be to permit the tolerance calculated for major species, including cattle, to be used with a tissue residue study in sheep to determine a

withdrawal time for new animal drugs to be used in sheep. The proposed rule is therefore expected to lower research expenses and provide an impetus for sponsors to submit supplemental NADA's for sheep. More specifically, it would eliminate the need for a total residue metabolism study that can be costly and prohibitive for sponsors of new animal drugs for small markets such as sheep. FDA believes this study is unnecessary in this instance due to the similarities in the metabolism of most drugs in cattle and sheep. Adopting the approach that allows for interspecies data extrapolation, along with the tissue residue depletion studies, would encourage NADA submissions by decreasing research costs while continuing to protect human food safety. Apart from these cost savings, FDA does not expect this proposal to impose any other compliance burdens on sponsors of new animal drugs.

IX. Regulatory Flexibility Analysis

The proposed rule is intended to reduce research costs for sponsors of NADA's for animal drugs used in sheep while maintaining the necessary safeguards concerning animal drug residues in human food. FDA estimates that this rule will not result in any compliance costs on the affected industry, regardless of the size of the companies involved. Further, FDA estimates that the rule will result in cost savings to sponsors of NADA's for animal drugs for use in sheep. In addition, most NADA sponsors would not be considered small businesses according to the standards of the Small Business Administration. Thus, in accordance with the Regulatory Flexibility Act, FDA certifies that this proposed rule would not have a significant economic effect on a substantial number of small entities.

X. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any 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 publication of the proposal to reclassify sheep as a minor species for all data collection purposes is not expected to result in expenditures of funds by State, local, and tribal governments or the private sector in excess of $100 million in any one year. Because the agency estimates no compliance costs and modest cost savings due to the proposed rule, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

XI. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XII. Comments

Interested persons may, on or before October 25, 1999, submit to the Dockets Management Branch (address above), written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration, ''Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species,'' Guidance No. 61, January 1999.

2. Short, C. R., ''Consideration of Sheep as a Minor Species: Comparison of Drug Metabolism and Disposition with Other Domestic Ruminants,'' *Veterinary and Human Toxicology*, vol. 36, No. 1, pp. 24–40, February 1994.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

2. Revise § 514.1 in paragraph (d)(1)(ii) to read as follows:

§ 514.1 Applications.

* * * * *

(d) * * *

(1) * * *

(ii) *Minor species* means animals other than cattle, horses, swine, chickens, turkeys, dogs, and cats.

* * * * *

Dated: July 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18926 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

[SPATS No. KS–021–FOR]

Kansas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of an amendment to the Kansas regulatory program (Kansas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Kansas is proposing to condense and revise its previously approved revegetation success guidelines. The amendment is intended to revise the Kansas program to be consistent with the corresponding Federal regulations and to improve operational efficiency.

This document gives the times and locations that the Kansas program and the amendment to that program are available for public inspection, the comment period during which you may submit written comments on the proposed amendment, and the procedures that will be followed for the public hearing, if one is requested.

DATES: We will accept written comments until 4:00 p.m., c.d.t., August 25, 1999. If requested, we will hold a public hearing on the amendment on August 20, 1999. We will accept requests to speak at the hearing until 4:00 p.m., c.d.t. on August 10, 1999.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to John Coleman, Mid-Continent Regional Coordinating Center, at the address listed below.

You may review copies of the Kansas program, the amendment, a listing of any scheduled public hearings, and all written comments received in response