Name	As styled in order
American Institute of Certified Public Accountants	American Institute of Certified Public Accountants.
Arthur Andersen, LLP	Arthur Andersen.
Cinergy Services, Inc.	Cinergy.
Cleco Corporation	Cleco.
Commonwealth Edison Company	Commonwealth Edison.
Consumers Energy Company	Consumers Energy.
Deloitte & Touche LLP	Deloitte & Touche.
Detroit Edison Company	Detroit Edison.
Edison Electric Institute	EEI.
FirstEnergy Corp	FirstEnergy.
Florida Public Service Commission	Florida Commission.
Mississippi Public Service Commission	Mississippi Commission.
National Association of Regulatory Utility Commissioners	NARUC.
National Rural Electric Cooperative Association	NRECA.
Old Dominion Electric Cooperative	Old Dominion.
PricewaterhouseCoopers, LLP	Price Waterhouse.
Public Service Electric & Gas Company of New Jersey	PSE&G.
Southern Company Services, Inc. (acting as agent for Alabama Power Company, Georgia Power Company, Gulf Power Company Mississippi Power Company and Savannah Electric and Power Company (collectively, Southern Company).	Southern.
Virginia Electric and Power Company	Virginia Power.

[FR Doc. 00–19507 Filed 8–2–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 99N–2151]

New Animal Drug Applications; Sheep as a Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reclassify sheep as a minor species for all data collection purposes. This reclassification will allow sponsors of 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 enable the extrapolation of the tolerances for residues of new animal drugs in cattle to sheep.

DATES: This rule is effective September 5, 2000.

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, e-mail: moeller@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 26, 1999 (64 FR 40321), FDA published a proposed rule to revise the definition of minor species in § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)) by deleting the following language: ''Sheep are a minor species with respect to effectiveness and animal safety data collection requirements; sheep are a major species with respect to human safety data collection requirements arising from the possible presence of drug residues in food.'' This change makes sheep a minor species for all data collection purposes in support of NADA's.

As stated in the preamble to the proposed rule (64 FR 40321), new data that have become available since publication of the minor species final rule (48 FR 1922, January 14, 1983) 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. While consumption levels can be a factor in determining whether a species should be classified as major or minor, the agency believes that the body of evidence concerning drug metabolism is more significant in determining the major/minor status of sheep than consumption data because it demonstrates the reliability of data extrapolated from cattle, a major species, to sheep.

II. Comments

FDA received seven comments on the proposed rule, six comments from organizations, and one from an individual. All the comments supported the proposed rule. The following is a summary of the comments:

(Comment 1) Six comments expressed the opinion that this change would lower research and development costs for sponsors seeking approval of new animal drugs for sheep.

(Comment 2) Six comments noted that the sheep industry suffers from a lack of animal drug availability to the detriment of the industry and animal health.

(Comment 3) Four of the comments praised the agency for its science-based approach to this issue.

Thus, FDA is adopting the rule as proposed.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), 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). The agency 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 a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory

options that would minimize any significant impact of a rule on small entities. FDA estimates that the final 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 in sheep. Because this final rule makes no mandates on other government entities and will result in expenditures less than $100 million in any one year, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Discussion

The benefit of this final rule will be to lessen the preapproval study requirements of NADA's for animal drugs to be used in sheep. It is therefore expected to lower research expenses and provide an impetus for sponsors to submit NADA's for minor use species rather than rely on extra-label use of animal drugs on sheep. More specifically, it would eliminate the need for a radio-labeled total residue 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. A more flexible approach that allows for this interspecies data extrapolation, along with the continued 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 final rule to impose any other compliance burdens on sponsors of new animal drugs.

FDA is amending the animal drug regulations to reclassify sheep as a minor species for all data collection purposes, thereby allowing extrapolation of data from closely related species such as cattle to sheep. Currently, FDA considers sheep as a minor species for the purpose of the data necessary to demonstrate animal safety and effectiveness only. It currently considers sheep as a major species for the purpose of human food safety requirements. Because new data have led FDA to believe there are not significant differences in the metabolism of most drugs between ruminant species, FDA is reclassifying sheep as a minor species for all data collection purposes. Thus, most data packages supporting an NADA for use in sheep will be able to rely on the required human food safety data collected for cattle.

V. 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. In the proposed rule, the agency mistakenly made this determination under 21 CFR 25.33(d)(4), which applies to action on minor species NADA's.

VI. The Paperwork Reduction Act of 1995

The NADA's regulation, § 514.1, contains collections of information requirements previously approved under OMB Control No. 0910–0032. FDA is amending the new animal drug regulation to reclassify sheep as a minor species for all data collection purposes. This reclassification does not change the reporting or recordkeeping burden, thus clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

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, 21 CFR part 514 is 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. Section 514.1 is amended by revising 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 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19627 Filed 8–2–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00P–1117]

Medical Devices; Anesthesiology Devices; Classification of Devices to Relieve Upper Airway Obstruction; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of June 23, 2000 (65 FR 39098). The document classified devices to relieve acute upper airway obstruction. These type devices were classified into class II. The preamble to the final rule correctly states that the devices were exempt from premarket notification, but this exemption was not reflected in the regulatory text. This document corrects that error.

DATES: This rule is effective August 3, 2000.

FOR FURTHER INFORMATION CONTACT: Carroll O'Neill, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262, ext. 170.

SUPPLEMENTARY INFORMATION: In FR Doc. 00–15864, appearing on page 39098 in the **Federal Register** of June 23, 2000, the following correction is made:

§ 868.5115 [Corrected]

On page 39099, in the third column, in § 868.5115 *Device to relieve acute upper airway obstruction*, in paragraph (b), insert at the end of the paragraph the sentence ''The device is exempt