relinquish the property to the security representative pending proper authorization for the possession of the property or its removal from the installation. The individual relinquishing the property will be provided with a receipt for the property.

§1204.1004 Trespass.

Unauthorized entry upon any NASA real property or installation is prohibited.

§ 1204.1005 Unauthorized introduction of firearms or weapons, explosives, or other dangerous materials.

- (a) The unauthorized carrying, transporting, or otherwise introducing or causing to be introduced, or using firearms or other dangerous weapons, explosives or other incendiary devices, or other dangerous instrument, substance, or material likely to produce substantial injury or damage to persons or property, into or upon NASA real property, facility, or installation, is prohibited.
- (b) Paragraph (a) of this section shall not apply to:
- (1) The lawful performance of official duties by an officer, agent, or employee of the United States, a State, or a political subdivision thereof, or NASA contractor, who is authorized to carry firearms or other material covered by paragraph (a) of this section.
- (2) The lawful carrying of firearms or other dangerous weapons at or on a NASA installation after written prior approval has been obtained from the installation Security Office in connection with sanctioned hunting, range practice, or other lawful purpose.

§ 1204.1006 Violations.

Please take notice that anyone violating these regulations may be cited for violating Title 18 of the United States Code (U.S.C.) Section 799, which states that whoever willfully shall violate, attempt to violate, or conspire to violate any regulation or order promulgated by the Administrator of the National Aeronautics and Space Administration for the protection or security of any laboratory, station, base or other facility, or part thereof, or any aircraft, missile, spacecraft, or similar vehicle, or part thereof, or other property or equipment in the custody of the Administration [NASA], or any real or personal property or equipment in the custody of any contractor under any contract with the Administration or any subcontractor of any such contractor, shall be fined under this title [Title 18],

or imprisoned not more than one year, or both.

Daniel S. Goldin,

Administrator.

[FR Doc. 00–19622 Filed 8–2–00; 8:45 am] **BILLING CODE 7510–01–U**

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 101

[Docket No. RM99-7-000; Order No. 618]

Depreciation Accounting

Issued July 27, 2000.

AGENCY: Federal Energy Regulatory

Commission, DOE. **ACTION:** Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending the General Instructions of 18 CFR part 101 to establish, for those public utilities and licensees that are subject to part 101, standards for determining depreciation for accounting purposes. The Commission also explains how it intends to monitor depreciation practices. This action is necessary in order to fulfill the Commission's statutory obligation to ensure that electric utilities charge proper amounts of depreciation to expense in each financial reporting period. The effect of this action will be to ensure that utilities allocate in a systematic and rational manner the cost of utility property to the periods during which the property is used in utility

DATES: This rule will be effective October 2, 2000.

FOR FURTHER INFORMATION CONTACT:

Wayne McDanal (Technical Information), Office of Finance, Accounting and Operations, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, (202) 219–2622

Joseph C. Lynch (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, (202) 208–2128

SUPPLEMENTARY INFORMATION:

Before Commissioners: James J. Hoecker, Chairman; William L. Massey, Linda Breathitt, and Curt Hebert, Jr.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is amending the General Instructions of 18 CFR Part 101 to establish, for those public utilities and licensees that are subject to Part 101, standards for determining depreciation for accounting purposes. The Commission also explains how it intends to monitor depreciation practices.

II. Background

On July 29, 1999, the Commission issued a Notice of Proposed Rulemaking (NOPR) proposing to establish the principles that public utilities and licensees subject to Part 101 must follow in determining depreciation rates for accounting purposes. In the NOPR the Commission noted that it has authority under Section 301 of the Federal Power Act (FPA) 2 over the accounting practices of public utilities and licensees and that, under this Section, it has prescribed a Uniform System of Accounts (USofA) 3 that these jurisdictional entities must follow.

The Commission further noted in the NOPR that it also has authority under Section 302 of the FPA 4 over the depreciation accounting practices of public utilities and licensees and that this authority includes the authority to determine and fix proper and adequate depreciation rates for accounting

purposes.

The Commission stated that, in order to fulfill its statutory obligation to ensure that electric utilities charge proper amounts of depreciation to expense in each financial reporting period, it had required public utilities and licensees to obtain Commission approval before changing their depreciation rates for accounting purposes.⁵ The Commission noted, however, that a decision of the U.S. Court of Appeals for the District of Columbia Circuit, Alabama Power Company, et al. v. FERC, 160 F.3d 7 (D.C. Cir. 1998) (Alabama Power), overturned the Commission's action in MidAmerican on procedural grounds.

The Commission began this rulemaking proceeding to respond to the court's concern that the Commission could not exercise its authority with respect to depreciation accounting matters without first establishing standards. The Commission thus proposed to require utilities ⁶ to use

¹ Depreciation Accounting, 64 FR 42304 (Aug. 4, 1999); FERC Stats. & Regs., Proposed Regulations ¶ 32,544 (July 29, 1999).

² 16 U.S.C. 825.

³ See 18 CFR Part 101.

^{4 16} U.S.C. 825a.

⁵ See MidAmerican Energy Company, 79 FERC ¶61,169 (1997), reh'g denied, 81 FERC ¶61,081 (1997) (*MidAmerican*).

⁶ As in the NOPR, henceforth when we use the word "utilities" in this final rule, we intend to

depreciation rates for accounting purposes that were based on the straight-line method of depreciation and the assets' estimated useful lives, the predominant method traditionally used by utilities. The Commission proposed, also, to monitor utility depreciation rates for accounting purposes on a caseby-case basis, e.g., as a result of or in conjunction with complaints or audits. The Commission's proposal to monitor depreciation practices and rates was in lieu of a requirement that utilities make individual filings and obtain prior Commission approval to change their depreciation rates for accounting purposes.

III. Comments Received

The Commission received 20 comments in response to the NOPR.7 The overwhelming majority of those comments agreed with the Commission's proposal not to require individual utilities to file their accounting depreciation rates with us for our approval.8 However, they strongly opposed the Commission's proposal to adopt the straight-line method of depreciation to the exclusion of other methods of depreciation that also result in systematically and rationally allocating the cost of utility property to the periods during which the utility uses the property in operations.

Only two Commenters, the Florida Public Service Commission and NARUC, supported the exclusive use of the straight-line method of depreciation,⁹ and NARUC asked for clarification of the inconsistency between this proposal and the accelerated cost recovery provisions that we have agreed to consider with respect to new transmission investment.¹⁰ All of the other Commenters opposed exclusive reliance upon the straight-line method of depreciation as the only permissible method of accounting for depreciation in the utility industry.

For example, the Edison Electric Institute (EEI) argued that the proposal is "inconsistent with the Commission's adopted policies promoting greater competition in electric markets * * *

[which require] a flexible approach to depreciation accounting * * notes that in an era of rapid technological change an asset's productivity may vary greatly over its service life. EEI suggests that, under such circumstances, accelerated depreciation will provide a better match of expenses to revenues than would straight-line depreciation. EEI notes that unregulated companies have the advantage of using accelerated depreciation to meet the changing needs of a free market economy; it asks that the Commission make the same advantages available to utilities as they enter the competitive era. 12

EEI urges the Commission to allow utilities the flexibility to meet the constantly changing conditions of the marketplace by permitting utilities to change the estimated service lives of their capital equipment and to adopt methods of depreciation other than straight-line, if, in their judgment, circumstances warrant. EEI points out that generally accepted accounting principles (GAAP) 13 allows for methods of depreciation other than straight-line that are also systematic and rational ways of accounting for the depreciable life of assets.¹⁴ According to EEI, this flexibility would permit companies to use depreciation schedules that incorporate service lives of varying lengths as well as varying rates of obsolescence. This would allow management to more carefully track costs and cost causation.

EEI submits that the proposed adoption of a straight-line depreciation method of accounting does not meet the reporting needs of a changing industry and runs counter to the Commission's efforts to promote efficient competition by reducing the regulatory and accounting burden on utilities. ¹⁵ EEI also observes that the NOPR's proposal for universal straight-line depreciation is inconsistent with the Commission's recent Order No. 2000, in which the Commission indicated that it would consider the application of accelerated

depreciation for new transmission investment.¹⁶

Detroit Edison submits that the Commission "is being far too prescriptive for an industry in transition and subject to competitive pressures." 17 According to Detroit Edison, GAAP mandates only that companies determine depreciation in a systematic and rational manner and recognizes several different methods of accounting for depreciation that would accomplish this.18 Detroit Edison also argues that straight-line depreciation necessarily defers the recognition of certain costs to future years, when, in a competitive environment, a company charging the higher prices necessary to recover these deferred costs could drive away customers. Detroit Edison submits that other methods of depreciation, such as double or 150-percent declining balance or sum-of-the-years digits depreciation, better match cost accrual with revenues and allow companies the flexibility to survive in a competitive world.¹⁹

Detroit Edison observes that the straight-line method of accounting for depreciation worked well when there was an obligation to serve and a guarantee of future income because technology changed little and customers had few options. Today, technology is changing rapidly, costs are becoming more differentiated, and choice is becoming the norm. As a result, the assumption that assets will produce a steady stream of revenue throughout their physical lives is no longer valid.

Rather, Detroit Edison submits, the assumption in today's world should be that each asset will produce a different, individual income stream, which will depend on its economic usefulness. Detroit Edison argues that "accounting should reflect that reality[]" 20 and help the industry prepare for competition rather than re-enforce existing

encompass both public utilities and licensees; we will refer to "utilities" for ease of reading. *See* 18 CFR Part 101, Definition No. 39.

⁷ A list of Commenters appears in the Appendix; we will refer to each Commenter by the short form listed there next to each name. The Mississippi Public Service Commission filed a notice of intervention, but did not comment.

 $^{^8}$ FERC Stats. & Regs. \P 32,544 at 33,808. See, e.g., EEI at 2.

 $^{^{9}\,\}mathrm{Florida}$ Public Service Commission at 3; NARUC at 5.

¹⁰ NARUC at 4.

 $^{^{\}rm 11}\,\rm EEI$ at 2.

¹² EEI at 16.

¹³ GAAP encompasses the conventions, rules and procedures necessary to define accepted accounting practices. GAAP incorporates the accounting profession's consensus at a particular time as to which economic resources and obligations companies should record as assets and liabilities, which changes in assets and liabilities they should record, how they should measure assets and liabilities and changes in them, what information they should disclose, how they should disclose it, and what financial statements they should prepare.

¹⁴ EEI at 18-19.

¹⁵ EEI at 4-6.

¹⁶ EEI at 21. In Order No. 2000, the Commission included as one of the innovative rate treatments offered to Regional Transmission Organization (RTO) participants non-traditional depreciation for ratemaking purposes for new transmission investments. RTOs would have to support their proposals with: (a) a detailed explanation of how the proposed rate treatment would help achieve the goals of Regional Transmission Organizations; (b) a cost-benefit analysis, including rate impacts; and (c) a detailed explanation of why the proposed rate treatment is appropriate for the RTO requesting it. See 18 CFR 35.34(e)(1), .34 (2)(iii); Regional Transmission Organizations, Order No. 2000, FERC Stats. & Regs. ¶31,089 at 31,194-95, order on reh'g, Order 2000-A, FERC Stats. &)Regs. ¶31,092 at

¹⁷ Detroit Edison at 2.

¹⁸ *Id.* at 2, 8.

¹⁹ *Id*.

²⁰ Id. at 10.

regulatory practices. ²¹ Most of the other Commenters expressed similar views. ²²

IV. Discussion

The Commission's Uniform System of Accounts for electric utilities defines depreciation as the loss of an asset's service value not restored by current maintenance.23 Some of the causes for the loss in service value include wear and tear, decay, action of the elements, inadequacy, obsolescence, changes in the art, changes in demand, and requirements of public authorities. The primary objective of recording depreciation expense is to allocate an asset's service value over its remaining useful life. To accomplish this objective the Commission has traditionally used a straight-line depreciation method to allocate an asset's service value over its remaining life.

We thus initially proposed to adopt for accounting purposes the straight-line method of depreciation as our standard. As we noted in the NOPR, straight-line depreciation was the method typically used by utilities.²⁴ While, in general, we expect that that is likely to continue to be the case for most utility property, commenters have persuaded us that requiring its universal use would be overly prescriptive. The primary objective of depreciation accounting is to allocate in a systematic and rational manner the cost of property to the periods during which the property is used in utility operations, *i.e.*, over its estimated useful service life. As Commenters correctly observe, there are methods of depreciation other than the straight-line method that also meet this objective.

Therefore, we will modify our proposed rule and simply require utilities to use for accounting purposes methods of depreciation that allocate the cost of utility property over its useful service life in a systematic and rational manner. Such methods include not only a straight-line method of depreciation, but other methods of depreciation. The broader systematic and rational standard will ensure that depreciation for accounting purposes is done properly while at the same time allowing flexibility in a changing business environment.

We are not unmindful that this additional flexibility could create a potential for abuse. However, we believe that our monitoring of utility depreciation practices will mitigate that potential. Consequently, as noted in the NOPR, we will not require utilities to make a separate filing to obtain Commission approval before implementing changes in depreciation rates for accounting purposes.²⁵ Instead,

(1973) ("Straight line is the predominant method used by utilities and sanctioned by most regulatory bodies."); Deloitte Haskins & Sells, Public Utilities Manual 23 (1980) ("[T]he straight-line concept is applied almost universally for both accounting and rulemaking. * * *''); C. Phillips, The Regulation of Public Utilities: Theory and Practice 272 (3d ed. 1993) (The straight line method * * * is the simplest and most commonly used."); L. Hyman, America's Electric Utilities: Past, Present and Future 292 (5th ed. 1994) ("The book depreciation rate is a straight line rate for most utility companies."); accord Depreciation Subcommittee of the NARUC Committee on Engineering, Depreciation, and Valuation of the National Association of Regulatory Utility Commissioners, Public Utility Depreciation Practices 12 (1968) ("In the two decades, since the Report of the Committee on Depreciation of the NARUC was published in 1943, the use of the straight-line method for accounting and rate-making purposes has became almost universal for public utilities.").

In addition, the FERC Annual Report Form No. 1's appeared to indicate the same.

we will monitor utility depreciation practices on a case-by-case basis.²⁶

V. Environmental Statement

The Commission excludes certain actions not having a significant effect on the human environment from the requirement to prepare an environmental assessment or an environmental impact statement.²⁷ The promulgation of a rule that is procedural or that does not substantially change the effect of legislation or regulations being amended raises no environmental considerations.²⁸ This final rule amends Part 101 of the Commission's regulations and does not substantially change the effect of the underlying legislation or the regulations being revised.

Further, approval of actions under Section 301 of the FPA, relating to accounting orders, also raises no environmental considerations.²⁹ The instant rule fundamentally involves accounting matters, establishing standardized depreciation accounting practices. Accordingly, no environmental consideration is necessary.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires rulemakings to contain either a description and analysis of the effect that the final rule will have on small entities or a certification that the rule will not have a significant economic impact on a substantial number of small entities.

In Mid-Tex Elec. Coop. v. FERC, 773 F.2d 327 (D.C. Cir. 1985), the court found that Congress, in passing the RFA, intended agencies to limit their consideration "to small entities that would be directly regulated" by proposed rules. Id. at 342. The court further concluded that "the relevant 'economic impact' was the impact of compliance with the proposed rule on regulated small entities." Id. at 342.

Most public utilities to which this final rule would apply do not fall within

²¹ Id. at 11.

²² See, e.g., American Institute of Certified Public Accountants at 1, 4; Commonwealth Edison at 1, 3-4, 7 (competition mandates various types of accounting for depreciation, including accelerated depreciation); Consumers Energy at 4-5 (Commission should allow all methods of accounting for depreciation, including accelerated depreciation, that result in a rational and systematic allocation of the cost of a utility's plant); PSE&G at 1 (under certain conditions methods of accounting for depreciation, other than straight-line, provide for a better matching of expenses with revenues); NRECA at 2 (changes in technology often require accelerated depreciation because of rapid obsolescence of assets); Cinergy at 1 (endorses comments of EEI); Allegheny Energy at 1 (the changing needs of the market place are affecting the useful lives of capital equipment and the rate at which equipment is becoming obsolete); Virginia Power at 6 (same); Old Dominion at 2 (GAAP recognizes other methods of accounting for depreciation that result in systematically and rationally recording depreciation expense over an asset's useful life.); AEP at 4 (proposed rule would impose more regulation and record keeping on the utility industry at the very time that it needs far less regulation in order to meet the demands of competition.); Arthur Anderson at 3 (depreciation accounting should be flexible to recognize the economic effects of regulation during the transition to a competitive business environment); Price Waterhouse at 1 (if the expected productivity or revenue-earning power or maintenance requirements vary greatly over the life of an asset, a depreciation method of accounting other than straight-line may more appropriately allocate costs to revenues); First Energy at 2 (the Commission should accept all methods of depreciation, including accelerated depreciation, that are consistent with GAAP); Deloitte & Touche at 2 (same); Southern at 13 (proposal runs counter to Commission's willingness to consider accelerated depreciation for new investment in transmission facilities).

²³ 18 CFR Part 101, Definition No. 12.

 $^{^{24}}$ See 64 FR 42304 (1999); FERC Stats. & Regs. $\P32,544$ at 33,806. See also, e.g., J. Suelflow, Public Utility Accounting: Theory and Application 96

²⁵ Our action today authorizes utilities to change their method of depreciation for accounting purposes *only*; it does not authorize any utility to change prices charged for power sales or transmission services (whether determined by stated rates or formula rates) to reflect a change in depreciation.

To change prices charged for power sales or transmission services (whether determined by

stated rates or formula rates) to reflect a change in depreciation, a utility would first have to make a filing with us, pursuant to sections 205 or 206, 16 U.S.C. 824d, 824e, as appropriate, to that effect.

 $^{^{26}}$ As we noted in Midwest Power Systems Inc., 67 FERC \P 61,076 at 61,209 (1994), utilities "most common[ly]" change their depreciation rates in the context of a rate case. $Accord,\,id.$ at 61,208, n.7.

We expect that utilities will continue to change their depreciation accounting predominantly in the context of rate cases, and that, in fact, changes in depreciation accounting will rarely occur outside of a rate case.

^{27 18} CFR 380.4.

^{28 18} CFR 380.4(a)(2)(ii).

^{29 18} CFR 380.4(a)(16).

the definition of small entity.³⁰ Consequently, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VII. Public Reporting Burden and Information Collection Statement

The Commission is amending 18 CFR part 101 to establish the principles for determining depreciation rates for accounting purposes. While we are adding an instruction to an information requirement, the instruction is not adding to the information reporting burden because the Commission is not requiring public utilities to do anything more or less than they are already doing to account for depreciation. Accordingly, this final rule does not impose any additional public reporting burden. We are forwarding a copy of this to the Office of Management and Budget for their information.

Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 [Attention: Michael Miller, Capital Planning and Policy Group, Phone: (202) 208–1415, Fax: (202) 208–2425, E-mail: mike.miller@ferc.fed.us].

To submit comments concerning collections of information and associated burden estimate(s), please send your comments to the contact listed above and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, [Attention: Desk Officer for the Federal Energy Regulatory Commission, Phone: (202) 395–3087, Fax: (202) 395–7285].

VIII. Document Availability

In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (http://www.ferc.fed.us) and in the Commission's Public Reference Room during regular business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First

Street, NE., Room 2A, Washington, DC 20426.

From FERC's Home Page on the Internet, this information is available in both the Commission Issuance Posting System (CIPS) and the Records and Information Management System (RIMS).

- —CIPS provides access to the texts of formal documents issued by the Commission since November 14, 1994.
- —CIPS can be accessed using the CIPS link or the Energy Information Online icon. The full text of this document is available on CIPS in ASCII and WordPerfect 8.0 format for viewing, printing, and/or downloading.
- —RIMS contains images of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

User assistance is available for RIMS, CIPS, and the Website during normal business hours from our Help line at (202) 208–2222, or by E-Mail (to WebMaster@ferc.fed.us) or the Public Reference Room at (202) 208–1371 (E-Mail to

public.referenceroom@ferc.fed.us).

During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Website are available. User assistance is also available.

IX. Effective Date

This final rule will take effect October 2, 2000. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this rule is not a "major rule" within the meaning of Section 251 of the Small Business Regulatory Fairness Act of 1996.³¹ The Commission will

submit the Final Rule to both houses of Congress and to the General Accounting Office.³²

List of Subjects in 18 CFR Part 101

Electric power, Electric utilities, Reporting and recordkeeping requirements, Uniform System of Accounts.

By the Commission.

David P. Boergers,

Secretary.

In consideration of the foregoing, the Commission amends Part 101, Title 18 of the Code of Federal Regulations, as follows.

PART 101—UNIFORM SYSTEM OF ACCOUNTS PRESCRIBED FOR PUBLIC UTILITIES AND LICENSEES SUBJECT TO THE PROVISIONS OF THE FEDERAL POWER ACT

1. The authority citation for Part 101 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7102–7352, 7651–7651o.

2. In Part 101, General Instructions, paragraph 22 is added to read as follows:

General Instructions

* * * *

22. Depreciation Accounting.

A. *Method*. Utilities must use a method of depreciation that allocates in a systematic and rational manner the service value of depreciable property over the service life of the property.

B. Service lives. Estimated useful service lives of depreciable property must be supported by engineering, economic, or other depreciation studies.

C. Rate. Utilities must use percentage rates of depreciation that are based on a method of depreciation that allocates in a systematic and rational manner the service value of depreciable property to the service life of the property. Where composite depreciation rates are used, they should be based on the weighted average estimated useful service lives of the depreciable property comprising the composite group.

Note: This appendix will not be published in the Code of Federal Regulations.

Appendix—Commenters

Name	As styled in order
Allegheny Energy, Inc	

³⁰ See 5 U.S.C. 601(3), citing to section 3 of the Small Business Act, 15 U.S.C. 632, which defines "small business concern" as a business that is

independently owned and operated and that is not dominant in its field of operation.

³¹ 5 U.S.C. 804(2).

^{32 5} U.S.C. 801(a)(1)(A).

Name	As styled in order
American Institute of Certified Public Accountants	American Institute of Cer- tified Public Accountants.
Arthur Andersen, LLP	Arthur Andersen.
Cinergy Services, Inc.	Cinergy.
Cleco Corporation	Cleco.
Commonwealth Edison Company	
Consumers Energy Company	
Deloitte & Touche LLP	Deloitte & Touche.
Detroit Edison Company	Detroit Edison.
Edison Electric Institute	EEI.
FirstEnergy Corp	
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	
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).	
Virginia Electric and Power Company	Virginia Power.

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

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.

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