Order. In addition, because the final rule is not a significant regulatory action as defined by the Executive Order and therefore 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. Because this rule requires no change in the current industry practice concerning the manufacture and use of this ingredient, the cost of compliance with this regulation is zero, and the potential benefits of the rule include the wider use of this substance to achieve the intended technical effects, 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.

VII. References

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

1. ''Potato-Derived Maltodextrins for Infants and Toddlers,'' W. A. Scholten's Chemical Factories' Brochure, Avebe Foxhol, 1941.

2. ''The Double Triangle,'' 3d Annual, no. 36, W. A. Scholten's Chemical and Potato Starch Factories and Meihuizen Boon's Factories, Holland, pp. 1–10, June 21, 1951.

3. Patent Specification no. 435,034, ''Improved Process for the Production of a Sugar Preparation from Starch, and for Manufacturing a Milk Suitable for Infants,'' United Kingdom, 1935.

4. Kuyk, P. G., and K. Schots, ''For Infant and Toddler,'' in ''The Book of Foods and Allied Products and of Substitutes During Wartime,'' 1942.

5. Campagne, J. vL., ''Feeding and Nutritional Derangements of Infants,'' Scientific Publisher of the Amsterdam Book and Newspaper Society, pp. 33, and 126–127, 1947.

6. Wolfram, M. L., and H. El Khadem, ''Chemical Evidence for the Structure of Starch'' in ''Starch: Chemistry and Technology,'' R. L. Whistler, and E. F. Paschall, eds. Academic Press, Inc., New York, pp. 251–278, 1965.

7. Schenck, F. W., and R. E. Hebeda, ''Starch Hydrolysis Products: An Introduction and History'' in *Starch Hydrolysis Products, Worldwide Technology, Production, and Applications*, F. W. Schenk, and R. E. Hebeda, eds., VCH Publishers, Inc., New York, pp. 1–21, 1992.

8. ''Evaluation of the Health Aspects of Starches and Modified Starches as Food Ingredients,'' Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1979.

9. Young, A. H., ''Fractionation of Starch'' in ''Starch,'' 2d ed., R. L. Whistler, and E. F. Paschall, eds., Academic Press, Inc., New York, pp. 249–283, 1984.

10. ''Unmodified Food Starches and Acid-Modified Starches; Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients,'' 50 FR 12821, April 1, 1985.

11. Food Chemicals Codex, 3d ed., 3d supp., p. 125, 1992.

12. Evans, R. B., and O. B. Wurzburg, ''Production and Use of Starch Dextrins'' in Starch: Chemistry and Technology, vol. 2, R. L. Whistler and E. F. Paschall, eds., Academic Press, Inc., New York, pp. 253-278, 1967.

13. ''Food Additives and Contaminants Committee Report on Modified Starches,'' United Kingdom Ministry of Agriculture, Fisheries and Food, FAC/REP/31, Her Majesty's Stationery Office, London, p. 5, 1980.

14. ''Definition of Maltodextrin,'' European Starch Associations, Circular Letter Stex 4/88, February 1988.

15. Memorandum dated September 11, 1989, from the Food and Color Additives Review Section, FDA to the Direct Additives Branch, FDA, ''Maltodextrin from Potatoes.''

16. ''Maltodextrins,'' Technical Bulletin No. 5.10.20.119EF, AVEBE Veenddam-Holland, April 1987.

17. Letter plus attachments, in response to a letter of July 13, 1978, from George W. Irving of the Select Committee on GRAS Substances, Federation of American Societies for Experimental Biology, Bethesda, MD, to Corbin Miles, Food and Drug Administration, Washington, DC, pp. 1-4, 1978.

18. ''Maltodextrins and Corn Syrup Solids,'' Technical Bulletin, A. E. Staley Manufacturing Co., Decatur, IL, Bulletin, July 1987.

19. Zuber, M. S., ''Genic Control of Starch Development'' in ''Starch: Chemistry and Technology,'' R. L. Whistler, and E. F. Paschall, eds., Academic Press, Inc., New York, pp. 43–62, 1965.

20. Whistler, R. L., and J. R. Daniel, ''Starch,'' in *Kirk-Othmer's Encyclopedia of Chemical Technology*, 3d ed., vol. 21, J. Brown, C. I. Eastman, C. Galojuch, A. Klingsberg, and M. Wainwright, eds., pp. 492–496, 1983.

21. ''Maltodextrin; Proposed Affirmation of GRAS Status as Direct Human Food Ingredient,'' 47 FR 36443, August 20, 1982.

22. ''Specifications for the Identity and Purity of Food Additives and Their Toxicological Evaluation,'' FAO Nutrition Meetings Report Series, no. 46 and WHO Technical Report Series, no. 445, pp. 13–14, 1970.

23. ''Toxicological Evaluation of Some Food Colours, Emulsifiers, Stabilizers, Anti-Caking Agents, and Certain Other Substances,'' FAO Nutrition Meetings Report Series, no. 46A, p. 62 and WHO/FOOD ADD./70.36, 1970.

24. ''Potato Facts,'' Economics Research Service, U.S. Department of Agriculture, Fall/Winter, 1988/89.

25. Memorandum dated October 17, 1989, from the Additives Evaluation Branch, FDA, to the Direct Additives Branch, FDA, ''Maltodextrin derived from potatoes.''

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1444 is amended by revising the second sentence in paragraph (a) and by revising paragraph (b) to read as follows:

§ 184.1444 Maltodextrin.

(a) * * *. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch or potato starch with safe and suitable acids and enzymes.

(b)(1) Maltodextrin derived from corn starch must be of a purity suitable for its intended use.

(2) Maltodextrin derived from potato starch meets the specifications of the Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capital St. NW., suite 700, Washington, DC 20408, or at the Division of Petition Control (HFS–217), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

* * * * *

Dated: September 6, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23352 Filed 9–20–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

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 Fermenta Animal Health Co. The ANADA provides for the use of a generic gentamicin solution for control of bacterial infections of the uterus (metritis) of horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: (September 21,1995.)

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153, is the sponsor of ANADA 200–023, which provides for the use of a generic gentamicin solution (100 milligrams/milliter (mg/mL)) for control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

ANADA 200–023 for Fermenta Animal Health Co.'s gentamicin sulfate solution (100 mg/mL gentamicin) is approved as a generic copy of Schering's Gentocin® Solution (100mg/mL gentamicin) in NADA 046–724. The ANADA is approved as of August 4, 1995, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 529

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 529 is amended to read as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing ''000061, 000856, 057561, and 058711'' and adding in its place ''000061, 000856, 054273, 057561, and 058711''.

Dated: September 5, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23353 Filed 9–20–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

RIN 1076–AC51

Land Acquisitions (Nongaming)

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule: correction.

SUMMARY: This document contains corrections to the final rule 25 CFR Part 151, which was published Friday, June 23, 1995, (Vol. 60, No. 121, FR 32874–32879). The regulations related to land acquisitions for nongaming purposes by an Indian individual or tribe.

EFFECTIVE DATE: September 21, 1995.

FOR FURTHER INFORMATION CONTACT: Alice A. Harwood, Chief, Branch of Technical Services, Division of Real Estate Services, Bureau of Indian Affairs, Room 4522, Main Interior Building, 1849 C Street, NW, Washington, DC 20240, Telephone No. (202) 208–3604.

SUPPLEMENTARY INFORMATION:

Background

The final rule that is the subject of these corrections modified three existing sections within Part 151 (Land Acquisitions) and created a new section which contained additional criteria and requirements used by the Secretary in evaluating requests for the acquisition of lands by the Untied States in trust for federally recognized Indian tribes when lands are outside and noncontiguous to the tribe's existing reservation boundaries.

Need for Correction

As published, the final rule contains errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication on June 23, 1995, of the final rule (25 CFR 151), FR Doc. 95–15215, is corrected as follows:

Part 151—LAND ACQUISITIONS (NONGAMING)

On page 32878, third column, in the title, delete ''(Nongaming)''.

§ 151.11 [Amended]

On page 32879, in the second column, in § 151.11, add ''(Nongaming)'' after ''acquisitions'' in the title.

On page 32879, in the second column, in § 151.11, line four of paragraph (b), insert ''as follows:'' after the word ''considered.''

On page 32879, in the second column, in § 151.11, line three of paragraph (d), insert ''as follows:'' after the word ''completed.''

Dated: September 7, 1995.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 95–23010 Filed 9–20–95; 8:45 am]

BILLING CODE 4310–02–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD13–95–039]

Safety Zone Regulation; Trojan Nuclear Plant, Rainier, OR, to Port of Benton, WA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a moving safety zone around the barge ZB–1801 and accompanying towboats as the vessels complete five separate transits through U.S. navigable waters between Rainier, Oregon, and Benton, Washington. A safety zone is needed to protect the barge ZB–1801 and accompanying