substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), FDA certifies that this final rule will not have a significant impact on a substantial number of small entities.

FDA received one comment to the analysis of the proposed rule regarding the potential impact on small entities. The comment suggested that if consumption shifts from raw to processed produce as a result of this rule, the impact on small farmers would be detrimental.

The comment did not provide any data with which FDA could evaluate the potential for shifts in consumption from raw to processed produce or any resulting impact on small farmers. FDA notes, however, that it is unlikely that this rule would cause consumption to shift from raw to processed produce. As stated previously, the likely substitution is from those fruits and vegetables that are too high in fat or sodium to qualify for the term ''healthy'' to those raw or processed fruits and vegetables that do qualify as ''healthy.''

FDA further notes that, even if demand for processed produce increased relative to raw produce, the impact on small farmers should not be detrimental. There is no reason to expect that small farmers would not be able to sell their produce to processors if the demand for processed produce increases.

Only those processed products that would meet the current definition of the term ''healthy'' other than the minimum nutrient contribution requirement will be affected by this rule. Because there is no change in the definition as it applies to those products currently using the term, only those entities desiring to take advantage of the new exemption will bear any cost of this regulation. No firm of any size will voluntarily bear the cost of changing a label to bear the term ''healthy'' unless doing so will be advantageous to the firm. Therefore, FDA concludes that no small entity will be adversely affected by this rule.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (61 FR 5349, February 12, 1996; corrected May 21, 1996 (61 FR 25421)). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

In the 1996 healthy proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling or other third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling provisions in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320(c)(2)).

VI. References

1. Karmas, E., and R. S. Harris, ''Nutritional Evaluation of Food Processing, 3d Ed.,'' Van Nostrand Reinhold Co., Inc., New York, chapters 3, 4, and 11, 1988.

2. Satchell, F. B., Division of Programs and Enforcement Policy (HFS–158), Center for Food Safety and Applied Nutrition, memorandum to file, September 22, 1995, Modification of USDA's Nutrient Data Base for National Nutrient Databank Release No. 9, ''Processed Fruit and Vegetable Products that Qualify to Bear the Term 'Healthy','' June 17, 1994, and July 17, 1995.

3. University of Illinois at Urbana-Champaign, Department of Food Science and Human Nutrition, ''Nutrient Conservation in Canned, Frozen and Fresh Foods,'' October 1997.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, 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 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.65 is amended by revising paragraph (d)(2)(iv) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) * * *

(2) * * *

(iv) The food contains at least 10 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed of vitamin A, vitamin C, calcium, iron, protein, or fiber, except for the following:

(A) Raw fruits and vegetables;

(B) Frozen or canned single ingredient fruits and vegetables and mixtures of frozen or canned single ingredient fruits and vegetables, except that ingredients whose addition does not change the nutrient profile of the fruit or vegetable may be added;

(C) Enriched cereal-grain products that conform to a standard of identity in part 136, 137, or 139 of this chapter.

* * * * *

Dated: March 18, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–7667 Filed 3–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 75N–0339]

Human and Veterinary Drugs; Current Good Manufacturing, Processing, Packaging, or Holding; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the current good manufacturing practice regulations for human and veterinary drug products to correct a typographical error. This action is being taken to ensure accuracy and clarity in the agency's regulations.

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has become incorporated into the agency's current good manufacturing practice regulations for human and veterinary drug products. In an amendment to 21 CFR 211.84, published on September 29, 1978 (43 FR 45014), the word ''date'' was inadvertently misspelled as ''data''. This document corrects that error. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has

determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374.

§ 211.84 [Corrected]

2. Section 211.84 *Testing and approval or rejection of components, drug product containers, and closures* is amended in paragraph (c)(5) by removing the word ''data'' and by adding in its place the word ''date''.

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7666 Filed 3–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Bambermycins; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulation for bambermycins to correct several cross-references in that regulation. In approving a new animal drug application (NADA) filed by Hoechst Roussel Vet, FDA failed to amend certain cross-references to conform to amendments in the approval document and to provide certain other cross-references. This document provides for those conforming amendments and cross-references.

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1739.

SUPPLEMENTARY INFORMATION: In amending the bambermycins regulation to reflect approval of Hoechst Roussel Vet's NADA 141–034 (use of bambermycins Type A medicated articles to make Type C medicated cattle feeds), FDA amended § 558.95 (21 CFR 558.95) by redesignating paragraph (b) as paragraph (d) (see 62 FR 8373, February 25, 1997), but failed to amend the cross-references in paragraph (a). Furthermore, in approving NADA 141–034 to establish several added uses in § 558.95(b)(4) (currently § 558.95(d)(4)) (see 59 FR 15624, April 4, 1994 and 61 FR 43654, August 26, 1996), FDA failed to provide reference in paragraph (a)(5) to uses in paragraphs (b)(4)(ii) and (b)(4)(iii) (current paragraphs (d)(4)(ii) and (d)(4)(iii)). Section 558.95 is amended by revising paragraph (a), by revising the cross-references to paragraphs (d)(1), (d)(2), (d)(3), and (d)(4), as appropriate, and by expanding those references in paragraph (a)(5) to reflect all uses in paragraph (d)(4).

List of Subjects in 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 and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.95 is amended by revising paragraph (a) to read as follows:

§ 558.95 Bambermycins.

(a) *Approvals.* To sponsors identified by drug labeler codes in § 510.600(c) of this chapter for use of bambermycins Type A medicated articles as bambermycins activity per pound in paragraph (d) of this section as follows:

(1) To 012799: 2, 4, and 10 grams for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) To 012799: 0.4 gram for use as in paragraph (d)(2) of this section.

(3) To 011490: 0.4 and 2 grams for use as in paragraph (d)(2) of this section.

(4) To 012286, 016968, and 017790: 0.4 and 2 grams for use as in paragraph (d)(2) and 2 grams for use as in paragraph (d)(3) of this section.

(5) To 012799: 10 grams to make 40 to 800 grams per ton Type B feed for use as in paragraph (d)(4) of this section.

* * * * *

Dated: March 12, 1998.

Andrew J. Beaulieau,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–7699 Filed 3–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

31 CFR Part 2

National Security Information

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: This rule revises regulatory text that identifies, by position title, senior Treasury officials authorized to originally or derivatively classify national security information under Executive Order 12958. These designations are now contained in Treasury Order 102–19, which is published in the **Federal Register**. This order will be updated as necessary to revise the designations of officials who have been delegated by the Secretary of the Treasury the authority to classify originally or derivatively national security information.

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: Robert A. McMenamin, Assistant Director (Information and Physical Security), Department of the Treasury, Office of Security, Room 3210 Annex, 1500 Pennsylvania Avenue, NW, Washington, D.C. 20220, (202) 622–1120.

SUPPLEMENTARY INFORMATION: This rule removes the specific designations of Treasury officials authorized to originally and derivatively classify national security information under Executive Order 12958 and previous Orders. The designation of such officials is now made by a Treasury Order that will be revised from time to time as may be necessary. This rule reduces costs by making it unnecessary to revise periodically the regulations in part 2.

Because this rule relates to agency management and personnel, notice and public procedure and a delayed effective date are not required pursuant to 5 U.S.C. 553(a)(2) and the provisions of Executive Order 12866 do not apply. Because notice and public procedure is not required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply.