received by NOAA, and there has been a low level of NOAA activity under the OTEC Act. During this 15 year period of time, the availability and relatively low price of fossil fuels, coupled with the risks to potential investors, has limited the interest in the commercial development of OTEC projects.

NOAA is authorized, consistent with the purposes and provisions of the OTEC Act, to amend or rescind the OTEC regulations. In particular, section 117 of the OTEC Act requires NOAA to review the regulations on a periodic basis. NOAA is authorized and directed to revise the regulation as necessary and appropriate to ensure that the regulations do not impede the development, evolution, and commercialization of OTEC technology.

Given that a commercial OTEC industry has yet to develop, Part 981 remains unused for the most part. Removal of Part 981 at this time is consistent with the purposes and provisions of the OTEC Act in that it will allow NOAA to evaluate the suitability of these regulations at such time as interest in the commercial development of OTEC projects occurs. At such time, NOAA will issue a proposed rule appropriate to the then current regulatory needs. Potential Licensees will therefore be assured that any future OTEC regulations will be up to date, and will continue to provide innovation and flexibility necessary for an emerging OTEC industry.

NOAA is mindful of its responsibility for licensing of commercial OTEC facilities and plantships under the OTEC Act, however, and will take appropriate steps to review and process an application should one be made. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide copies of the provisions of these OTEC regulations in response to such inquiries. Thus, NOAA will provide actual and timely notice of applicable procedures and requirements to particular individuals. *See* 5 U.S.C. 552(a). Accordingly, NOAA is removing Part 981, the OTEC regulations, from Title 15 of the CFR.

III. Miscellaneous Rulemaking Requirements

Executive Order 12612: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant the preparation of a Federalism Assessment under Executive Order 12612.

Executive Order 12866: Regulatory Planning and Review

This regulatory action is not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

No licenses have been issued for OTEC projects under 15 CFR Part 981. When commercial interest in OTEC projects occurs, NOAA will issue a proposed rule appropriate to the regulatory needs at that time. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide actual and timely notice of applicable procedures and requirements to particular individuals. *See* 5 U.S.C. 552(a). For these reasons, the removal of Part 981 is not expected to have a significant economic impact on a substantial number of small entities, and the Assistant General Counsel for Legislation and Regulation of the Department of Commerce has so certified to the Chief Counsel for Advocacy of the Small Business Administration. As such, a Regulatory Flexibility Analysis was not prepared.

Paperwork Reduction Act

This regulatory action does not contain an information collection requirement subject to review and approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3500 *et seq.*

National Environmental Policy Act

NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the human environment. No applications for licenses of commercial OTEC facilities or plantships have yet been received by NOAA, and Part 981 remains unused for the most part. When commercial interest in OTEC projects occurs, NOAA will issue a proposed rule appropriate to the regulatory needs at that time. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide actual and timely notice of applicable procedures to particular individuals. *See* 5 U.S.C. 552(a). Therefore, and environmental impact statement is not required.

Authority: Ocean Thermal Energy Conversion Act of 1980, as amended, 42 U.S.C. 9101 *et seq.*

List of Subjects in 15 CFR Part 981

Administrative practice and procedures, Energy, Environmental protection, Intergovernmental relations, Marine resources, Penalties, Reporting and recordkeeping requirements.

Dated: May 2, 1996.

David Evans,

Acting Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, Chapter IX of Title 15 of the Code of Federal Regulations is amended as follows:

PART 981—OCEAN THERMAL ENERGY CONVERSION LICENSING PROGRAM—[REMOVED]

1. Under the authority of the Ocean Thermal Energy Conversion Act of 1980, Part 981 is removed.

[FR Doc. 96–11464 Filed 5–8–96; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0216]

Food Labeling: Nutrient Content Claim for ''Extra''; 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 March 22, 1996 (61 FR 11730). The document authorizes the use, on food labels and in food labeling, of the term ''extra'' as a synonym for the term ''added.'' The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: March 22, 1996.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

In FR Doc. 96–6942, appearing on page 11730 in the Federal Register of Friday, March 22, 1996, the following corrections are made:

1. On page 11730, in the third column, in the first full paragraph, in the first line, the date ''March 21, 1995'' is corrected to read ''March 21, 1994''.

2. On page 11731, in the first column, under section ''V. Public Comment'', in the second paragraph, the fifth line, the first word, ''proposal'', is corrected to read ''final rule.''

Dated: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11516 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Medetomidine Hydrochloride Injection; Change of Sponsor Name

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 a new animal drug application (NADA) filed by Orion Corp. ORION–FARMOS. The NADA provides for the use of medetomidine hydrochloride injection in dogs for its sedative and analgesic properties. The regulations are also amended to reflect a change of sponsor name.

EFFECTIVE DATE: May 9, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Orion Corp. ORION–FARMOS, (formerly Orion Corp. FARMOS), P.O. Box 425, SF–20101 Turku, Finland, filed NADA 140–999, which provides for intravenous or intramuscular use of Domitor® (medetomidine hydrochloride) injection as a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The drug product is available by prescription. The application is approved as of March 19, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1335 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Additionally, the firm has informed FDA that it has changed its corporate name from Orion Corp. FARMOS to Orion Corp. ORION–FARMOS. Accordingly, the agency is also amending 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 19, 1996, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the sponsor name ''Orion Corp. FARMOS, Research and Development, Pharmaceuticals,'' and by adding in its place ''Orion Corp. ORION–FARMOS'', and in the table in paragraph (c)(2) in the entry for ''052483'' by removing the sponsor name ''Orion Corp. FARMOS, Research and Development, Pharmaceuticals,'' and adding in its place ''Orion Corp. ORION–FARMOS''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

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

4. New § 522.1335 is added to read as follows:

§ 522.1335 Medetomidine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use.* As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations.* Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severly debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 15, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–11511 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Halofuginone Hydrobromide, Bacitracin Methylene Disalicylate

AGENCY: Food and Drug Administration, HHS.