availability of dietary supplement powders with no more than the equivalent of 0.12 percent weight-to-weight elemental iron are such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, or ingesting such substance. Accordingly, the Commission voted to grant the petition and proposed to amend 16 CFR 1700.14(a)(13) to exempt from requirements for child resistant packaging those dietary supplement powders with no more than the equivalent of 0.12 percent weight-to-weight elemental iron. 60 FR 17660 (April 7, 1995).

After considering all available and relevant information, the Commission determines to issue the proposed exemption on a final basis.

G. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), when an agency issues proposed and final rules, it must examine the rules' potential impact on small businesses. The Act requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis if a proposed rule would have a significant impact on a substantial number of small businesses, small organizations, and small governmental jurisdictions.

When the Commission proposed to exempt powdered iron-containing dietary supplements from CRP requirements, it found that the exemption would not have any significant economic impact on a substantial number of small entities. The exemption will give manufacturers of these products the option of packaging products using any packaging they choose. As far as CPSC is aware, powdered iron-containing dietary supplements are not currently packaged in CRP. The Commission's Compliance staff is exercising its enforcement discretion regarding these products pending completion of this rulemaking. Thus, the exemption will bring no change in the current packaging of products subject to the exemption. The Commission is not aware of any information that would alter its conclusion that this exemption will not have any significant economic effect on a substantial number of small entities.

H. Environmental Considerations

The Commission's regulations at 16 CFR 1021.5(c)(3) state that rules exempting products from child-resistant packaging requirements under the PPPA normally have little or no potential for affecting the human environment. The Commission did not foresee any special or unusual circumstances surrounding the proposed rule and found that exempting these products from the PPPA requirements would have little or no effect on the human environment. For this reason, when the Commission issued the proposed exemption, it concluded that no environmental assessment or impact statement is required in this proceeding. That conclusion remains unchanged.

I. Effective Date

Because this rule provides for an exemption, no delay in the effective date is required. 5 U.S.C. 553(d)(1). Accordingly, the rule shall become effective upon publication of the final rule in the Federal Register.

List of Subjects in 16 CFR Part 1700

Consumer protection, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

Conclusion

For the reasons given above, the Commission amends Title 16 of the Code of Federal Regulations to read as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: 15 U.S.C. 1471–1476. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. Section 1700.14(a)(13) is revised to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

(13) *Dietary supplements containing iron.* Dietary supplements, as defined in § 1700.1(a)(3), that contain an equivalent of 250 mg or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Preparations in which iron is present solely as a colorant; and

(ii) Powdered preparations with no more than the equivalent of 0.12 percent weight-to-weight elemental iron.

* * * * *

Dated: October 6, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Reference Documents

The following documents contain information relevant to this rulemaking proceeding and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Washington, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814.

1. Briefing Memorandum with attached briefing package, March 14, 1995.
2. Memorandum from Sandra E. Inkster, Ph.D., HSPS, to Jacqueline N. Ferrante, Ph.D., HSPS, ''Review of Iron Toxicity: Relevance to a Petition Requesting Exemption for Powdered, Iron-Containing Dietary Supplements,'' February 15, 1995.
3. Memorandum from Catherine A. Sedney, EPHF, to Jacqueline N. Ferrante, Ph.D., HSPS, ''Petition to Exempt Iron-Containing Supplement Powders from PPPA Requirements,'' February 16, 1995.
4. Memorandum from Marcia P. Robins, EPSS, to Jacqueline N. Ferrante, Ph.D., HSPS, ''Preliminary Market Information: Petition for Exemption from Child-Resistant Packaging Requirements for Powdered Iron-Containing Dietary Supplements,'' March 10, 1995.
5. Briefing Memorandum with attached briefing package, September 19, 1995.
6. Memorandum from Marcia P. Robins, EPSS, to Jacqueline N. Ferrante, Ph.D., HSPS, Final Regulatory Flexibility Act Issues: Petition for Exemption from Child-Resistant Packaging Requirements for Powdered Iron-Containing Dietary Supplements,'' July 5, 1995.

[FR Doc. 95–25322 Filed 10–16–95; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Decoquinate

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 supplemental new animal drug application (NADA) filed by Rhone-Poulenc, Inc. The supplemental NADA provides for use of decoquinate Type A medicated articles to make Type C medicated feeds for young sheep for the prevention of certain forms of coccidiosis.

EFFECTIVE DATE: October 17, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary

Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Rhone-Poulenc, Inc., 500 Northridge Rd., suite 620, Atlanta, GA 30350, filed supplemental NADA 39–417, which provides for use of Deccox® (decoquinate) Type A medicated article to make a Type C medicated feed for young sheep for the prevention of coccidiosis caused by *Eimeria bakuensis*, *E. crandallis*, *E. ovinoidalis*, and *E. parva*.

The supplemental NADA is approved as of August 28, 1995, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 28, 1995, because the supplemental NADA contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to the use for which the supplemental NADA is approved.

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 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.195 is amended in paragraph (d) in the table by numerically adding a new entry to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
13.6 (0.0015 pct)	.....	Young sheep; for the prevention of coccidiosis caused by *Eimeria ovinoidalis*, *E. crandallis*, *E. parva*, *E. bakuensis*.	Feed Type C feed at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food.	011526
*	*	*	*	*

Dated: October 5, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–25623 Filed 10–16–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 573

[Docket No. 86F–0060]

Food Additives Permitted In Feed and Drinking Water of Animals; Selenium

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for comment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal food additive regulations concerning the approved use of selenium as a food additive to suspend those amendments resulting from promulgation of a September 13, 1993, stay. This suspension conforms to certain provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1994, and the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. This interim rule amends the selenium food additive regulation to provide for the conditions set forth in these laws.

DATES: This interim regulation is effective October 17, 1995. Submit written comments by January 16, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION:

I. Background

A. 1987 Amendments

In the Federal Register of April 6, 1987 (52 FR 10887), and corrected on June 4, 1987 (52 FR 21001), FDA issued a final rule amending the selenium food additive regulation (21 CFR 573.920) to increase the maximum amount of selenium supplementation permitted in animal feeds. The action was based on