

Agriculture, Nutrition, and Forestry, United States Senate, July 1979, p. 59.

2. Kokoski, C. J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intra-gastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

4. "Bioassay of 1,4-Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI-CG-TR-80, 1978.

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxide (EO) and 1,4-Dioxane (DX)."

Any person who will be adversely affected by this regulation may at any time on or before October 6, 1986, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.3400 is amended in paragraph (c) by alphabetically inserting a new item in the list of substances to read as follows:

§ 178.3400 Emulsifiers and/or surface-active agents.

* * * * *
(c) * * *

List of substances	Limitations
Alpha-sulfo-omega-(dodecyloxy)poly(oxyethylene) ammonium salt (CAS Reg. No. 30174-67-5).	For use only as an emulsifier at levels not to exceed 0.3 percent by weight of styrene-butadiene copolymer coatings for paper and paperboard complying with § 178.170 of this chapter.

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Dated: August 28, 1986.

John M. Taylor,
Acting Associate Commissioner for Regulatory Affairs.
[FR Doc. 86-19998 Filed 9-4-86; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Parts 357 and 369

[Docket No. 79N-0378]

Anthemintic Drug Products for Over-the-Counter Human Use; Final Monograph

Correction

In FR Doc. 86-17180, beginning on page 27756, in the issue of Friday, August 1, 1986, make the following correction:

On page 27759, third column, after § 357.180, "Part 396" should read "Part 369".

BILLING CODE 1505-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Salinomycin, Roxarsone, and Bacitracin Zinc

AGENCY: Food and Drug Administration.
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 International Minerals & Chemical Corp., providing for safe and effective use of previously approved salinomycin, roxarsone, and bacitracin zinc Type A medicated articles to make Type C medicated broiler chicken feeds. The feeds are used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency.

EFFECTIVE DATE: September 5, 1986.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: International Minerals & Chemical Corp., P.O. Box 207, Terre Haute, IN 47808, filed NADA 139-190 providing for combining the following previously approved Type A articles: Bio-Cox® containing 30 grams of salinomycin sodium per pound with 3-Nitro® containing 10, 20, 50, or 80 percent roxarsone, and Baciferin® containing 10, 25, 40, or 50 grams of bacitracin zinc activity per pound. The Type A articles are combined to make Type C broiler feeds containing salinomycin at 40 to 60 grams per ton, roxarsone at 34.1 grams per ton (0.00375 percent), and bacitracin zinc at 10 to 50 grams per ton. The feeds are used for prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and increased rate of weight gain and improved feed efficiency. The NADA is approved and the regulations are amended accordingly. 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. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(ii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.