(i) The alcohol-insoluble solids maximums specified in § 155.170(b)(1)(vi) do not apply.

(ii) The skins of not more than 25 percent by count of the peas in the container are ruptured to a width of 1.6 millimeters (0.06 inch) or more.

(2) If the quality of canned dry peas falls below the standard of quality prescribed by paragraph (b)(1) of this section, the label shall bear the statement of substandard quality in the manner and form specified in § 155.170(b)(3) for canned peas, except that the words "Excessively mealy" shall not be used.

(c) *Fill of container.* (1) The standard of fill of container for canned dry peas is that prescribed for canned peas by § 155.170(c).

(2) If canned dry peas fall below the standard of fill of container prescribed by paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

6. By revising § 155.190(b)(3) and by redesignating § 155.190(c)(2) as (c)(3) and adding a new paragraph (c)(2) to read as follows:

§ 155.190 Canned tomatoes.

* * * * *

(b) * * *

(3) Determine compliance as specified in § 155.3(b).

* * * * *

(c) * * *

(2) Determine compliance as specified in § 155.3(b).

(3) If canned tomatoes fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 28, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin August 26, 1980, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1981 shall fully comply. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: June 20, 1980.

Note.—Incorporation by reference approved by the Director of the Office of the Federal Register on March 11, 1976, and is on file in the Federal Register Library.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–19369 6–26–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 310

[Docket No. 79N–0177]

New Drugs; Sweet Spirits of Nitre Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document contains the final decision that any drug product containing sweet spirits of nitre is not generally recognized as safe effective and is misbranded for over-the counter (OTC) human use. Any sweet spirits of nitre drug product marketed for OTC use will be subject to regulatory action unless it is the subject of an approved new drug application. The Food and Drug Administration (FDA) is taking this action after considering all the available evidence which was set forth in the preamble to the proposal published in the **Federal Register** of February 22, 1980 (45 FR 11846). This final rule is part of FDA's ongoing review of OTC drug products.

EFFECTIVE DATE: June 26, 1980.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 22, 1980, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), FDA issued a proposal to establish a regulation for OTC sweet spirits of nitre drug products, together with the conclusions and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), the data and information considered by the Panel were put on display in the Hearing Clerk's office, Food and Drug Administration (FDA), Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of small amounts of information considered confidential.

In the preamble to the proposed regulation, FDA advised that it would not follow the full OTC rulemaking procedure set forth in § 330.10 (21 CFR 330.10) because the agency determined that use of any drug product containing sweet spirits of nitre for any purpose is contrary to the public interest and that action to remove all products containing sweet spirits of nitre from the market should be implemented expeditiously. The agency also advised that a final rule under the proposal would become effective on the date of publication in the **Federal Register.** Interested persons were invited to file, on or before March 24, 1980, written comments regarding the proposed rule. No comments were received. Because of the risk to the public health involved in the use of sweet spirits of nitre drug products, the Commissioner has found that there is good cause to have this final rule become effective on the date of publication, as authorized by 5 U.S.C. 553(d)(3) and by 21 CFR 10.40(c)(4)(ii). This final rule contains the agency's final decision on OTC sweet spirits of nitre drug products and is effective immediately.

Sweet spirits of nitre contains between 3.5 and 4.5 percent of ethyl nitrite in alcohol and is also known as spirit of nitre, spirit of nitrous ether, and ethyl nitrite spirit. It has been marketed OTC for use as a diaphoretic to reduce fevers in children, as a diuretic, and as an intestinal antispasmodic for the treatment of flatulent colic in infants. It has also been used topically for cold sores and fever blisters. The agency has

reviewed the available data and information on sweet spirits of nitre and is aware of no scientific evidence to support its effectiveness for any use. There is evidence that severe and/or fatal methemoglobinemia may ensue if sweet spirits of nitre is ingested. The risk of poisoning for infants due to some undeveloped enzyme systems and to the increased level of fetal hemoglobin (Ref. 1) are major factors in the agency's assessment that sweet spirits of nitre is not safe for OTC use.

Based on the available evidence, the agency is making a final determination that sweet spirits of nitre cannot be generally recognized as safe and effective for any OTC use. If the labeling of any drug product represents or suggests it to contain sweet spirits of nitre for any OTC use, that product will be considered misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) and a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) for which an approved new drug application, under section 505 of the act (21 U.S.C. 355) and Part 314 of the regulations (21 CFR Part 314), is required for marketing. In the absence of an approved new drug application, any such drug product in interstate commerce after the effective date of this final rule will be subject to regulatory action. The agency is unaware of any sweet spirits of nitre drug product that is the subject of an approved new drug application.

In addition, because of the risk associated with the use of sweet spirits of nitre, the agency intends to request firms to recall to the retail level all drug products containing sweet spirits of nitre.

Reference

(1) Chilcote, R. R., et al., "Sudden Death of an Infant from Methemoglobinemia After Administration of 'Sweet Spirits of Nitre'," *Pediatrics*, 59:280–282, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 310 by adding new § 310.525, to read as follows:

§ 310.525 Sweet spirits of nitre drug products.

(a) Historically, sweet spirits of nitre has been present as an ingredient in over-the-counter (OTC) drug products for various uses. Based upon the lack of adequate data to establish effectiveness for any use and the adverse benefit-to-risk ratio, sweet spirits of nitre drug products cannot be considered generally recognized as safe and effective. The benefit from using sweet spirits of nitre for any use is insignificant when compared to the risk.

(b) Any drug product containing sweet spirits of nitre is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is a new drug within the meaning of section 201(p) of the act for which an approved new drug application under section 505 of the act and Part 314 of this chapter is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FDA–1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that any preparation containing sweet spirits of nitre for any use is safe and effective for the purpose intended.

(d) Any drug product containing sweet spirits of nitre in interstate commerce after June 27, 1980, that is not in compliance with this section is subject to regulatory action.

Effective date. This rule shall be effective on June 27, 1980.

(Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704))

Dated: June 20, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–19323 Filed 6–26–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 522

Disophenol Sodium; Implantation or Injectable Dosage Form; New Animal Drugs Not Subject to Certification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulation for disophenol sodium injection to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data. These conditions of use were classified as effective as a result of a National Academy of Sciences/National Research Council, Drug Efficacy Study Group (NAS/NRC) evaluation of the product. In lieu of certain effectiveness data, approval may require submission of bioequivalence or similar data. A previous **Federal Register** publication has reflected that this product is in compliance with the conclusions of the review.

EFFECTIVE DATE: June 27, 1980.

FOR FURTHER INFORMATION CONTACT: Henry C. Hewitt, Bureau of Veterinary Medicine (HFV–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3430.

SUPPLEMENTARY INFORMATION: The NAS/NRC review of this product was published in the **Federal Register** of February 1, 1969 (34 FR 1610). In that document, the Academy concluded, and FDA concurred, that the product was effective for the removal of certain hookworms from dogs.

That announcement was issued to inform holders of new animal drug applications (NADA's) of the findings of the Academy and the agency, and to inform all interested persons that such articles could be marketed if they were the subject of approved NADA's and otherwise complied with the requirements of the Federal Food, Drug, and Cosmetic Act.

American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, responded to the notice by submitting a supplemental NADA (12–598V) providing current information covering manufacturing and controls and revising the labeling for the safe and effective use of the product for treating dogs infested with certain hookworms. The supplemental application was approved by a regulation published in the **Federal Register** of October 13, 1972 (37 FR 21632). The regulation reflecting this approval established a new section for the drug (21 CFR 135b.71, recodified as 21 CFR 522.740). The new section did not specify those conditions of use that were NAS/NRC approved.

This document amends the regulation to indicate those conditions of use for which approval for identical products in dogs need not include certain types of efficacy data required for approval by § 514.111(a)(5)(vi) of the new animal drug regulations. In lieu of those data, approval of such products may be obtained if bioequivalency or similar data are submitted as suggested in the guideline for submitting NADA's for generic drugs reviewed by the NAS/NRC. The presently approved use of the product in cats is based on effectiveness data which is proprietary, and new