(2) In the second column of page 11845, the thirteenth line of paragraph (d) of § 184.1763 now reading ". . . in § 170.3(n)(10) of this chapter; 0.15 . . ." should have read as follows:

". . . in § 170.3(n)(9) of this chapter; 0.1 percent for dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.15 . . ."

BILLING CODE: 1505-01-M

## 21 CFR Part 310

[Docket No. 79N-0177]

### Sweet Spirits of Nitre for Over-the-Counter Human Use

*Correction*

In FR Doc. 80-5325 appearing on page 11846 in the issue of Friday, February 22, 1980, make the following corrections:

In the third column of page 11846, in the third complete paragraph, in the eighth and twelfth lines, "Internal Panel" should have read "External Panel". Also, in the last line of the paragraph ". . . use unnecessary." should have read "use is unnecessary."

BILLING CODE: 1505-01-M

## 21 CFR Part 320

[Docket No. 79N-0477]

### Carbonic Anhydrase Inhibitors; Bioequivalence Requirements

*Correction*

In FR Doc. 80-5207 appearing on page 11849 in the issue of Friday, February 22, 1980, make the following corrections:

(1) In column three of page 11849, delete the footnote "Milligrams per day" from Table 2.

(2) In the third column of page 11850, Table 5, the third item in the "$T_{max}$" column now reading "2.9" should have read "2.0".

(3) The first line of the top of the first column of page 11851 should be completed as follows:

". . . of the new formulation with the old product and a solution of an . . ."

(4) In the second column of page 11851, three lines above Table 8, ". . . show on gross . . ." should have read ". . . show no gross . . .".

(5) In the third column of page 11851, in the last line of the first paragraph, "ethozazolamide" should have read "ethoxazolamide".

(6) In the eighth line of the fourth paragraph ". . . 0.1 *N* NCl . . ." should have read ". . . 0.1 *N* HCl . . .".

(7) In the first column of page 11852, in the ninth line of the paragraph designated "1", ". . . ($T_{max}$ of the absorption . ." should have read ". . . ($T_{max}$) or the absorption . . .".

BILLING CODE: 1505-01-M

## 21 CFR Part 348

[Docket No. 78N-0301]

### External Analgesic Drug Products for Over-the-Counter Drug Use; Establishment of a Monograph and Notice of Proposed Rulemaking; Correction

**AGENCY:** Food and Drug Administration.

**ACTION:** Correction of proposed rule.

**SUMMARY:** The agency is making corrections to FR Doc. 79-36583, relating to external analgesic drug products for over-the-counter drug use published at 44 FR 69768, December 4, 1979.

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

**SUPPLEMENTARY INFORMATION:** The Food and Drug Adminstration issued in the **Federal Register** of December 4, 1979 (44 FR 69678) a proposed rule regarding external analgesic drug products for over-the-counter drug use. The document would add a new Part 348 (21 CFR Part 348) to Chapter I of Title 21 of the Code of Federal Regulations. A correction document was published in the **Federal Register** of February 5, 1980 (45 FR 7820). This document makes further corrections. The following changes are made:

1. On page 69768 column 1, under "Dates," change "March 6, 1980" to "March 3, 1980."

2. On page 69771, column 2, line 15, delete "Benzethonium chloride."

3. On page 69776, column 3, reference (4), change "]. C. Hardy" to "J. D. Hardy."

4. On page 69782, column 2, reference (2), change "Beautner" to "Beutner."

5. On page 69786, column 3, last line in the table, insert superscript "1" after "Triethanolamine salicylate."

6. On page 69788, column 1, last line in the first complete paragraph, delete "(CM)."

7. On page 69840, column 1, reference (7), change "McKay" to "MacKay."

8. On page 69845, column 3, line 21, change "hydroscopic" to "hygroscopic."

9. On page 69845, column 3, line 23, insert "(Ref. 1)" after "hydration."

Dated: March 17, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-9022 Filed 3-24-80; 8:45 am]

BILLING CODE 4110-03-M

## 21 CFR Part 357

[Docket No. 79N-0379]

### Exocrine Pancreatic Insufficiency Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Extension of Time for Comments and Reply Comments

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule; extension of comment periods.

**SUMMARY:** The Food and Drug Administration (FDA) extends the comment period to April 21, 1980, and extends the reply comment period to May 21, 1980, on the proposal to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) exocrine pancreatic insufficiency drug products. This action is being taken to allow more time for the collection and assessment of data to provide more meaningful comments on the issue.

**DATES:** Written comments by April 21, 1980, and reply comments by May 21, 1980.

**ADDRESS:** Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 21, 1979 (44 FR 75666), FDA proposed to establish conditions for the safety, effectiveness, and labeling of exocrine pancreatic insufficiency drug products for over-the-counter (OTC) human use. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until March 20, 1980, to comment on the proposal and until April 21, 1980, for reply comments.

In response to the proposal, the Cystic Fibrosis Foundation requested a 30-day extension of the comment period. This extension of the comment period was

requested to allow the Cystic Fibrosis Foundation sufficient time to develop a response to the Panel's recommendation that pancrelipase (now available only by prescription) be available over-the-counter. In support of its request, the Cystic Fibrosis Foundation pointed out that the "information copy" (preliminary final draft) of the Panel's report dated October 1978 did not alert persons to a change in the status of pancrelipase because the recommendation was not made by the Panel until the November 17–19, 1978 meeting. The Cystic Fibrosis Foundation also advised that its organization is a voluntary health agency with a very limited budget and a small staff and that could not respond quickly to issues of this type.

FDA has carefully considered the request. Because the comments of the Cystic Fibrosis Foundation will be in the public interest, the agency considers an extension of the comment period for 30 days to be appropriate.

Accordingly, the comment period is extended to April 21, 1980, and the reply comment period is extended to May 21, 1980. Comments may be seen in the office of the Hearing Clerk, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 17, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-8864 Filed 3-19-80; 3:43 pm]

BILLING CODE 4110-03-M

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## 21 CFR Part 357

**[Docket No. 79N-0379]**

## Exocrine Pancreatic Insufficiency Drug Products for Over-the-Counter Human Use; Establishment of Monograph; Notice of Proposed Rulemaking; Correction

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule; correction.

**SUMMARY:** In FR Doc. 79–39110 appearing at page 75666 in the issue of December 21, 1979, the changes listed below should be made.

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

**SUPPLEMENTARY INFORMATION:**

1. On page 75667, last paragraph of the second column, change "Category II" to "Category III."

2. On page 75667, in the third column, under "C. General Discussion" in the third line, change "ensymes" to "enzymes."

3. On page 75668, in the first column, in Reference (1), change volume "23" to "296."

4. On page 75668, in the second column, the last sentence of paragraph 2 should be reworded as follows: "At the present time the Panel is not aware of any such combination product which would satisfy the above requirements."

5. On page 75668, in the third column, in Reference (2) change volume "23" to "296."

6. On page 75669, in the first column, in Reference (3), change "Handscom" to "Hanscom."

Dated: March 17, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-8898 Filed 3-24-80; 8:45 am]

BILLING CODE 4110-03-M

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## DEPARTMENT OF LABOR

## Occupational Safety and Health Administration

## 29 CFR Part 1926

**[Docket No. S–107]**

## Entry and Work in Confined Spaces

**AGENCY:** Occupational Safety and Health Administration, U.S. Department of Labor.

**ACTION:** Advance Notice of Proposed Rulemaking.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) requests information of value in the development of standards for entry to, work in, and rescue from confined spaces in construction. Continuing reports of deaths and injuries to employees working in and rescuing employees from such work areas have been received by the Agency.

**DATES:** Comments should be received by May 31, 1980.

**ADDRESS:** Communications should be mailed to the Docket Officer, Docket S–107, Occupational Safety and Health Administration, U.S. Department of Labor, Room S6212, 200 Constitution Avenue, NW., Washington, D.C. 20210. The communications received will be available for public inspection and copying at the above location, between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Paul J. Bouley, Office of Construction and Civil Engineering Safety Standards, Occupational Safety and Health Administration, Room 3457, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210, (202) 523–8161.

**SUPPLEMENTARY INFORMATION:** OSHA announced its intention to develop a proposal covering confined spaces in general industry in an Advance Notice of Proposed Rulemaking (ANPR) published on October 19, 1979 (44 FR 60334). In that notice, OSHA stated that information available to the Agency included continuing reports of death and serious injury attributable to working in confined spaces. OSHA also noted that it had received 107 responses to a previous ANPR published on July 25, 1975 (40 FR 30980) which had also requested data and recommendations for revisions to OSHA standards covering confined spaces in all industries. Based on information available to the Agency, OSHA believes that the hazards of work in confined spaces are also significant in the construction industry. Therefore, OSHA is developing a proposal to revise its existing standards in order to effectively cover hazards connected with these activities in construction.

In consideration of the diversity and complexity of the issues, OSHA has decided to request information of value to the development of its proposal on confined spaces in construction. "Confined spaces" include storage tanks, boilers, ventilation and exhaust ducts, underground utility vaults, sewers, and open top spaces more than 4 feet in depth such as pits and vaults.

This notice is intended to elicit comment and information covering confined spaces only in the construction industry. However, comments and data concerning conditions and hazards common to general industry and construction, as well as those unique to construction, are requested. Specifically, for consderation in the development of a proposed standard covering construction, the Agency is seeking information and answers to the following questions.

1. Currently, certain OSHA standards apply to confined spaces in construction. Reference to confined or enclosed spaces is made in the following sections: §§ 1926.21(b)(6), 1926.154(a)(2), 1926.350(b)(4), 1926.352(g), 1926.353(b), 1926.353(c) and 1926.354(c)(1). Additionally other sections in Part 1926 are related to hazards that may be encountered when working in confined spaces. These include §§ 1926.103(b)(3), 1926.104, 1926.250(b)(2), 1926.651(v),