(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 "J. 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