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## 21 CFR Part 346

[Docket No. 80N-0050]

Anorectal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Correction

AGENCY: Food and Drug Administration.
ACTION: Proposed rule; Correction.

SUMMARY: The Food and Drug
Administration issued in the Federal
Register a proposal on over-the-counter
anorectal drug products. Various errors
appeared in the document. Changes are
made to correct them.

FOR FUTHER INFORMATION CONTACT: Agnes Black, Federal Register Writer (HFC-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: In FR Doc. 80–15334 appearing at page 35576 in the Federal Register of May 27, 1980, the following corrections are made:

1. At page 35673, second column, in § 346.3(b) and (e), change "buring" to "burning."

2. At page 35673, third column, in § 346.14 in the introductory text, change "Active" to "active" and in paragraph (e), change "Gylcerin" to "Glycerin."

3. At page 35674, first column, in § 346.18 in the introductory text, change "limit" to "limits" and in paragraph (a) change "percent" to "per."

4. At page 35674, first column, in \$ 346.20 in the introductory text, change "limit" to "limits" and in paragraph (b), add "percent" after "3" so that it read "Resorcinol 1 to 3 percent per dosage unit."

5. At page 35674, third column, in § 346.50 in paragraph (c)(7)(ii) in the third line, change "device" to "devices."

6. At page 35676, first column, in \$ 346.56 in paragraph (b)(18), change "alumina gel" to "aluminum hydroxide gel"; in paragraph (c)(1), change "alumina gel" to "aluminum hydroxide gel"; in paragraph (c)(2) in the fourth line, add "a" so that the line reads "final formulation as a separate ingredient"; and in the third column in paragraph (d)(1), change "alumina gel" to read "aluminum hydroxide gel."

7. At page 35676, third column, in § 346.58(c) in the second line, change "products" to "product."

8. At page 35677, first column, in \$346.60(d)(3), change "product" to "products."

Dated: July 14, 1980.

William F. Randolph,

Acting Associate Commissioner for
Regulatory Affairs.

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## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 349

[Docket No. 80N-0145]

Ophthalmic Drug Products for Overthe-Counter Human Use; / Establishment of a Monograph; Proposed Rulemaking; Correction

In FR Doc. 80–13750 appearing on page 30002 in the issue of May 6, 1980, make the following correction:

1. On page 30003, second column, in the fourteenth line, "until February 1978," should have read "until October 1976,".

2. On page 30006, first column, tenth line from the bottom, "ETA" should have read "EDTA". In the third column, the second line of paragraph "3. Antioxidant.", the word "determination" should have read "deterioration".

3. On page 30019, the second column, the ninth line from the bottom reading "marked" should have read "marketed". In the third column the third line of paragraph numbered "(5)" under References should have read "Chemist and Aerosol News, 36:43-46, 1965.", and the third line of paragraph "(8)" should have read "Optician, 3:9-2, 1974."

4. On page 30039, first column, twentythird line, the second word should have read "acuity". In the fifth line from the bottom "223" should have read "233".

In the second column, the second line of paragraph "a," under "Category I Labeling", the word "coreal" should have read "corneal".

5. On page 30041, first column, the third and forth line of paragraph "(9)" should have read "Vehicles on "H Thymidine in Normal Rabbit Corneas," Ophthalmologica, 156:425-436, 1968.

6. On page 30048, the second column, in the last line of § 349.14(d), the figure reading "0.0" should have read "0.2".

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