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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

Display Date 6-25-03  
Publication Date 6-26-03  
Certifier A. Corbin

[Docket No. 78N-036D]

RIN 0910-AA01

**Antidiarrheal Drug Products for Over-the-Counter Human Use; Final  
Monograph; Correction**

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule; correction.

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**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of April 17, 2003 (68 FR 18869). That document issued a final monograph that established conditions under which over-the-counter (OTC) antidiarrheal drug products (to control the symptoms of diarrhea) are generally recognized as safe and effective and not misbranded as part of its ongoing review of OTC drug products. The document published with an inadvertent error. This document corrects that error.

**DATES:** The rule is effective April 19, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mary S. Robinson or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

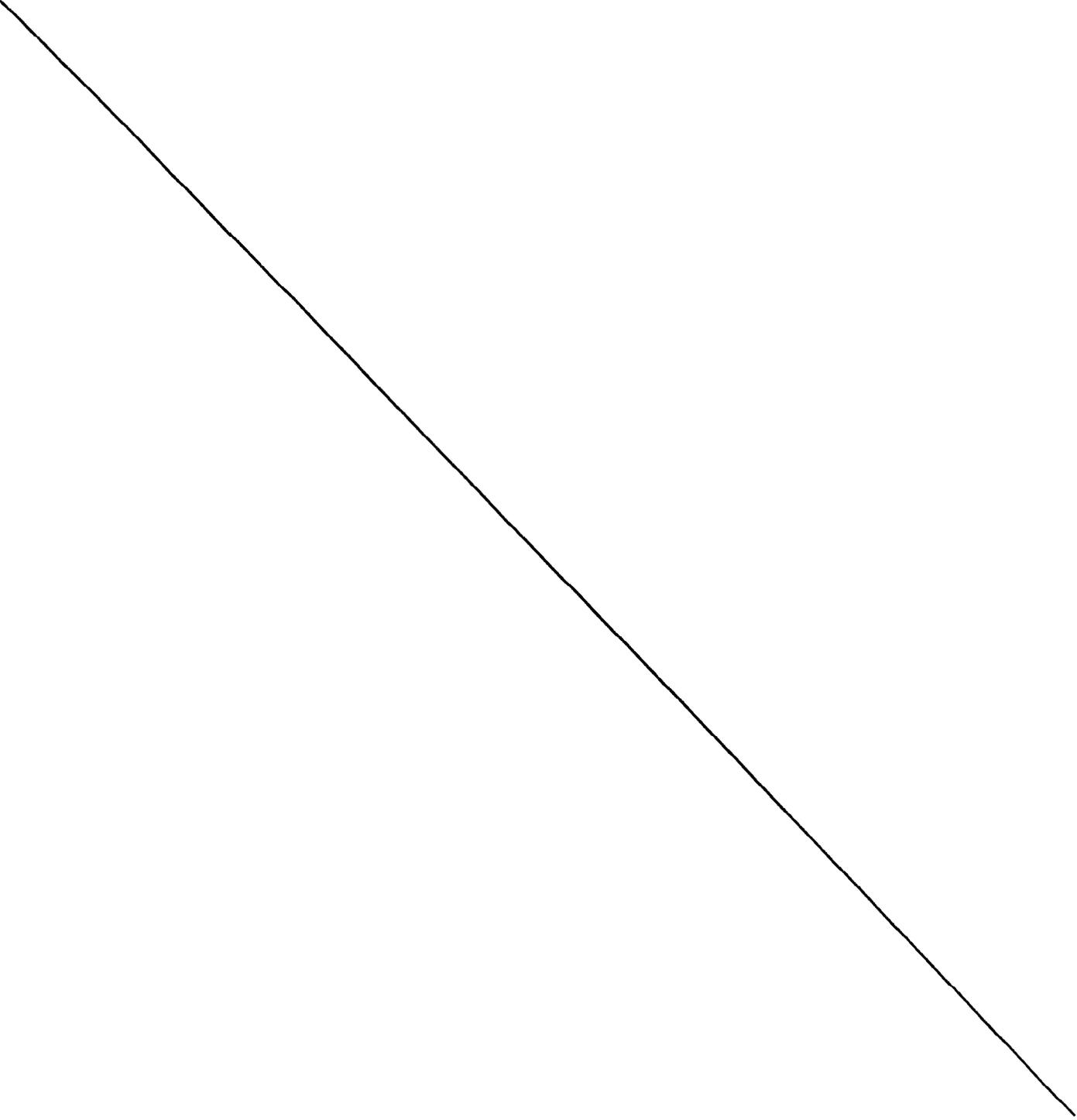
**SUPPLEMENTARY INFORMATION:** In FR Doc. 03-9380, appearing on page 18869 in the **Federal Register** of Thursday, April 17, 2003, the following correction is made:

**78N-036D**

**NCR**

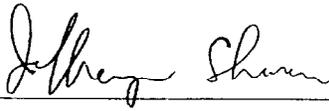
**§ 310.545 [Corrected]**

On page 18881, in the first column, in § 310.545 *Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses*, in paragraph (d)(1), in line 8, “(a)(18)(i)(A) of this section” is corrected to read “(a)(18) of this section (except as covered by paragraph (d)(22) of this section).”



Dated: 6/19/03  
June 19, 2003.

cd03109



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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