

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Food and Drug Administration

21 CFR Part 341

[Docket No. 76N-052G]

RIN 0910-AA01

**Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for Combination Drug Products; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**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 December 23, 2002 (67 FR 78158). The document issued a final monograph that established conditions under which over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic (cough-cold) combination drug products are generally recognized as safe and effective and not misbranded as part of its ongoing review of OTC drug products.

**DATES:** The regulation is effective December 23, 2004.

**FOR FURTHER INFORMATION CONTACT:** Cazemiro R. Martin 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. 02-32158 appearing on page 78158 in the **Federal Register** of Monday, December 23, 2002, the following corrections are made:

oc0382

**76N-052G**

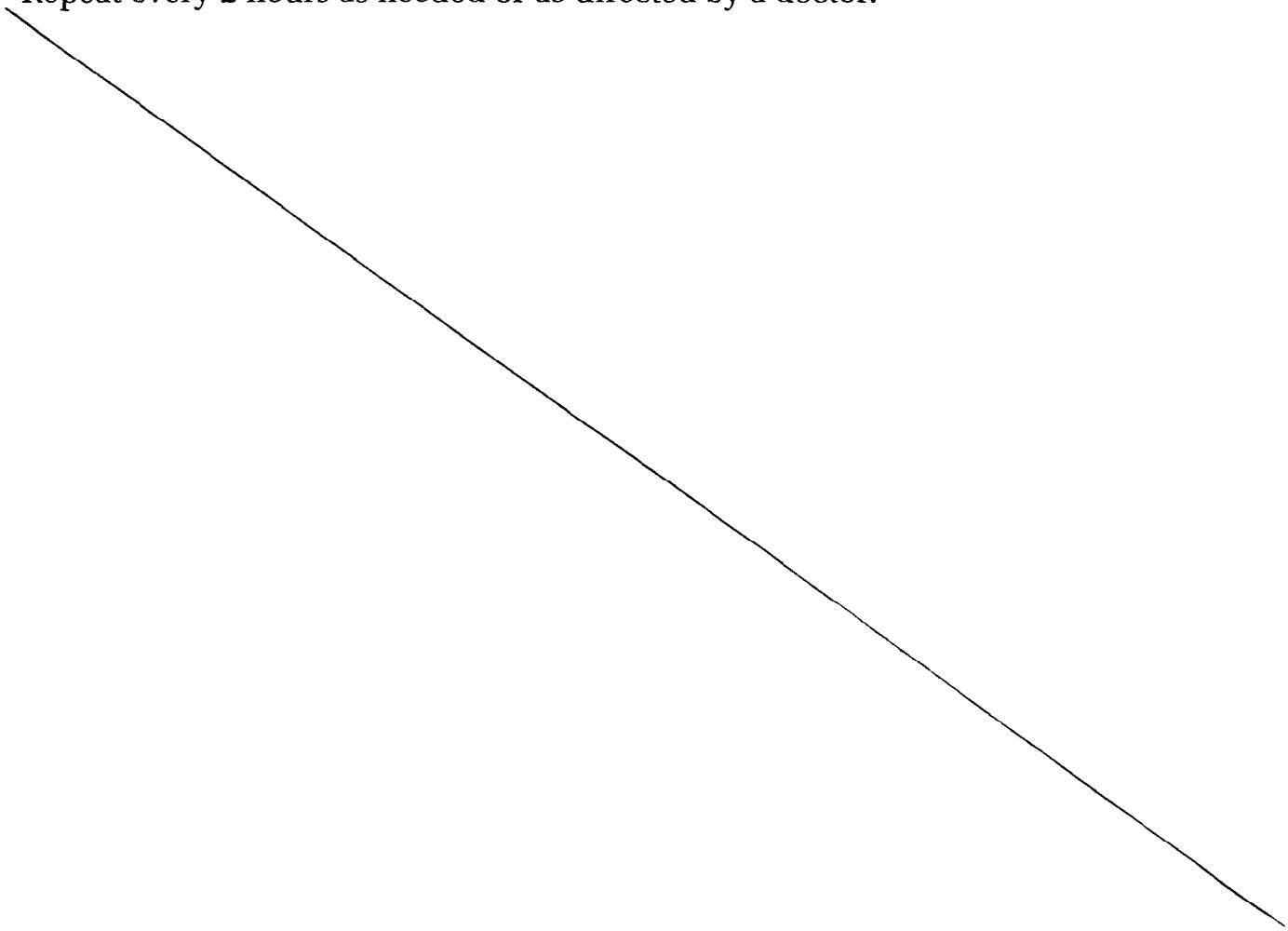
**NCR-2**

**§ 341.40 [Corrected]**

1. On page 78168, in the second column, in Part 341 *Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use*, under the authority citation, in amendment 2, “Section 341.40 is added to subpart C to read as follows:” is corrected to read “Section 341.40 is added to subpart B to read as follows:”

**§ 341.70 [Corrected]**

2. On page 78170, in the second column, in § 341.70 *Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product)*, in paragraph (b), “Repeat every hour as needed or as directed by a doctor.” is corrected to read “Repeat every 2 hours as needed or as directed by a doctor.”



Dated: 4, 8, 03

April 8, 2003.

*Jeffrey Shuren*

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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

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*Dawn P. Hawkins*