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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

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Certifier J. Cooke

[Docket Nos. 1978N-0021 and 1978N-021P]

RIN 0910-AF42

**Skin Protectant Drug Products for Over-the-Counter Human Use; Final
Monograph; Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) published a document in the **Federal Register** of June 4, 2003 (68 FR 33362), that established a final monograph with conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective and not misbranded as part of FDA's ongoing review of OTC drug products. That final monograph included OTC skin protectant drug products for minor cuts, scrapes, burns, chapped skin and lips, poison ivy, poison oak, poison sumac, and insect bites. That document also amended the regulation that lists nonmonograph active ingredients by adding those OTC skin protectant ingredients that were found to be not generally recognized as safe and effective. However, that document had an incorrect "approved as of" date (May 7, 1991, instead of November 10, 1993) in § 310.545(a)(18)(v)(A) and (a)(18)(vi)(A) in part 310 (21 CFR part 310) and incorrectly added paragraphs (a)(18)(ii) through (a)(18)(vi)(A) to § 310.545(d)(1) when those paragraphs should have been included in § 310.545(d)(11). This document corrects those errors.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: 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:

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

■ 2. Section 310.545 is amended by revising paragraphs (a)(18)(v)(A) and (a)(18)(vi)(A) headings and paragraphs (d)(1) and (d)(11) to read as follows:

§310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(18) * * *

(v) * * *

(A) *Ingredients—Approved as of November 10, 1993.*

* * * * *

(vi) * * *

(A) *Ingredients—Approved as of November 10, 1993.*

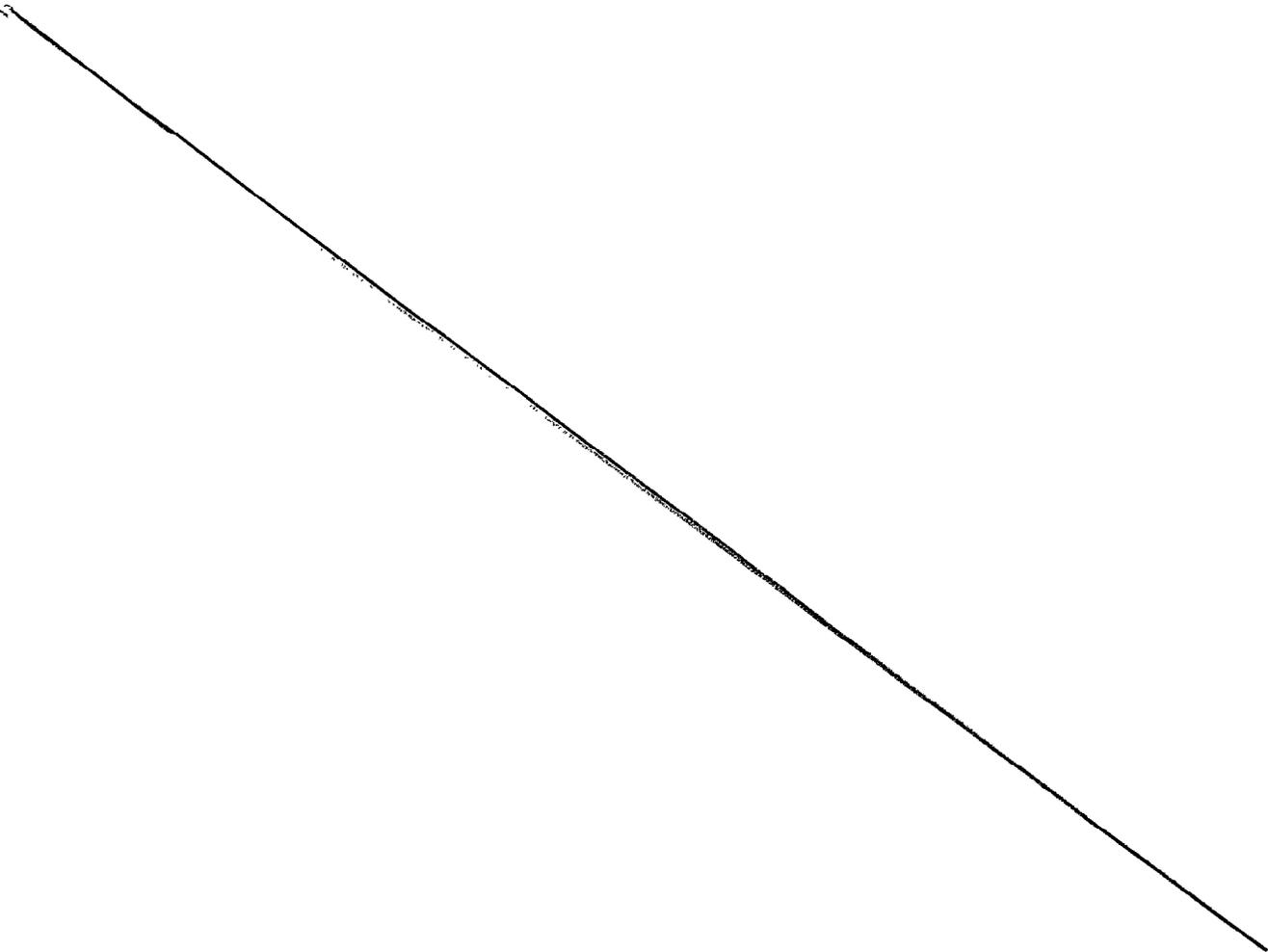
* * * * *

(d) * * *

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4)(i), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18)(i)(A).

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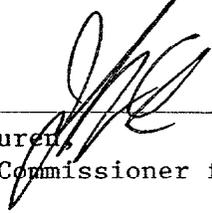
(11) November 10, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) (except products that contain ferric



subulfate as covered by paragraph (d)(22) of this section) through (a)(18)(v)(A), (a)(18)(vi)(A), (a)(22)(ii), (a)(23)(i), (a)(24)(i), and (a)(25) of this section.

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Dated: 8/11/04
August 11, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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