DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310


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 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 August 19, 2004.

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:


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.

(d) * * *


(11) November 10, 1993, for products subject to paragraphs (a)(6)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) (except products that contain ferric subsulfate as covered by paragraph (d)(22) of this section) through (a)(18)(vi)(A), (a)(18)(vi)(A), (a)(22)(ii), (a)(23)(i), (a)(24)(i), and (a)(25) of this section.

37 CFR Part 2

[Docket No. 2003–T–023]

RIN 0651–AB67

Changes in the Requirements for Amendment and Correction of Trademark Registrations


ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (“Office”) is amending its rules to eliminate the requirement that a request for amendment or correction of a registration be accompanied by the original certificate of registration or a certified copy thereof, and the requirement that an application to surrender a registration be accompanied by the original certificate or a certified copy.


FOR FURTHER INFORMATION CONTACT: Cheryl Black, Office of the Commissioner for Trademarks, by telephone at (703) 308–8910, ext. 153; or by e-mail to cheryl.black@uspto.gov.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Rule Making was published in the Federal Register (68 FR 70482) on December 18, 2003. No public hearing was held. Two organizations, two law firms and two attorneys submitted written comments.

The Office is amending its rules to eliminate the requirement that the original certificate of registration or a certified copy thereof accompany a request for amendment of a registration, a request for correction of a registration, or an application to surrender a registration for cancellation.

References below to “the Act,” “the Trademark Act,” or “the statute” refer to the Trademark Act of 1946, 15 U.S.C. 1051 et seq., as amended.

Requirement for Submission of Original Certificate of Registration or Certified Copy

The Office is eliminating the requirement under §§ 2.173, 2.174, and 2.175(b) that a request for amendment or...