

Federal Drug Administration (FDA)

Colloidal Oatmeal is classified as a skin protectant by the FDA according to 21 CFR Part 310 and 347 in *Skin Protectant Drug Product Over-the-Counter Human Use: Final Monograph*

Excerpts from the Federal Register/Vol. 69, No. 160 / Thursday, August 19, 2004 / Rules and Regulations follow:

(e) This amendment becomes effective on September 3, 2004.

Note 2: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD No. UF-2004-023(A), dated February 6, 2004, and AD No. F-2004-023, dated March 3, 2004.

Issued in Fort Worth, Texas, on August 4, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04-18438 Filed 8-18-04; 8:45 am]

BILLING CODE 4910-13-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[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 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:

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).

* * * * *

(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 subsulfate 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.

* * * * *

Dated: August 11, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-18975 Filed 8-18-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 2

[Docket No. 2003-T-023]

RIN 0651-AB67

Changes in the Requirements for Amendment and Correction of Trademark Registrations

AGENCY: United States Patent and Trademark Office, Commerce.

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 for cancellation be accompanied by the original certificate or a certified copy.

DATES: Effective September 20, 2004.

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

correction of a registration under section 7 of the Trademark Act be accompanied by the original certificate of registration or a certified copy thereof. Under the current rules, the Office attaches an updated registration certificate showing the amendment or correction to the original certificate and returns it to the registrant. However, the Office believes that requiring the registrant to submit the original certificate or a certified copy for the purpose of physically attaching an updated registration certificate, only to return the original certificate (or certified copy thereof) to the owner of record is unnecessary and inefficient. Instead, the Office will send the updated registration certificate showing the amendment or correction to the registrant, and instruct the registrant to attach it to the certificate of registration. The Office will update its own records to show the amendment or correction and attach an updated registration certificate to the printed copy of the registration on file in the Office.

The Office is also eliminating the requirement under § 2.172, that an application for surrender of a registration for cancellation under section 7 of the Trademark Act be accompanied by the original certificate, if not lost or destroyed. The requirement is unnecessary and inefficient. The Office will process a request for cancellation regardless of whether the original registration certificate accompanies the request. If the original certificate is submitted, the Office will destroy the certificate once the registration is cancelled.

One-Year Time Limit for Requests for Correction of Registrations

The proposed amendment to §§ 2.174 and 2.175 required registrants to file all requests for correction of a registration within one year after the date of registration, even where a mistake in a registration resulted from an Office error. This change in practice was proposed because granting requests to correct errors in registrations years after the date of registration caused confusion to examining attorneys and third parties who might have previously searched Office records and relied on information about existing registrations.

Four comments stated that many of the mistakes go unnoticed for years after issuance and are not discovered until it is time to file an affidavit of use or excusable nonuse under Section 8 of the Trademark Act. In an example provided by one commenter, a registrant received an error-free registration certificate and years later after preparing an affidavit of use discovered an error on the

registration in the Office's Trademark electronic database. Two comments stated that denying requests to correct errors in registrations after the one-year limit could result in the loss of substantive trademark rights and that maintaining a registration with inaccurate information could cause problems for registrants in establishing a complete chain of title, seeking foreign and international trademark rights, and protecting against trademark infringement. Accordingly, the Office has reconsidered this proposed change and at this time is not imposing a time limit for requests for corrections to registrations under §§ 2.174 and 2.175. The benefits of providing accurate information about registrations in the records of the Office, protecting the rights of owners to seek correction of errors in registrations and avoiding possible loss of substantive trademark rights due to mistakes in the registration outweigh the concerns that would warrant a time limit on filing requests for corrections.

Discussion of Specific Rules

The Office is amending §§ 2.172, 2.173, 2.174, 2.175, and 2.176.

The Office is amending § 2.172 to eliminate the requirement that an application to surrender a trademark registration for cancellation be accompanied by the original certificate of registration.

The Office is amending § 2.173 to eliminate the requirement that the original certificate of registration or a certified copy thereof accompany a request for amendment of a trademark registration.

The Office is amending § 2.174 to eliminate the requirement that the original certificate of registration or a certified copy thereof accompany a request for correction of a mistake by the Office in a trademark registration pursuant to section 7(g) of the Trademark Act.

The Office is amending § 2.175 to eliminate the requirement that the original certificate of registration or a certified copy thereof accompany a request for correction of a mistake by a registrant in a trademark registration pursuant to section 7(g) of the Trademark Act.

The Office is amending § 2.176 to change "Examiner of Trademarks" to "Post Registration Examiners."

Rule Making Requirements

Regulatory Flexibility Act

The changes in this final rule relate solely to the procedure to be followed in requesting an amendment or

correction of a registration. Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure under 5 U.S.C. 553(b)(A), and prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). See *Bachow Communications Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are "rules of agency organization, procedure, or practice" and exempt from the Administrative Procedure Act's notice and comment requirement); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (the rules of practice promulgated under the authority of former 35 U.S.C. 6(a) (now in 35 U.S.C. 2(b)(2)) are not substantive rules (to which the notice and comment requirements of the Administrative Procedure Act apply)); *Fressola v. Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) ("it is doubtful whether any of the rules formulated to govern patent and trade-mark practice are other than 'interpretative rules, general statements of policy, * * * procedure, or practice'" (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Rep. 149, 153 (1948))).

Nevertheless, the Office published a notice of proposed rule making in the **Federal Register**, 68 FR 70482 (Dec. 18, 2003), and in the Official Gazette of the United States Patent Office on January 13, 2004, in order to solicit public participation with regard to this rule package. Pursuant to the notice of proposed rule making, the Deputy General Counsel for General Law of the United States Patent and Trademark Office certified to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of section 605(b) of the Regulatory Flexibility Act that the proposed rule would not have a significant economic impact on a substantial number of small entities. No comments were received which referenced any impact the proposed rules would have on small entities.

This final rule package does not impose any new fees on members of the public. In fact, because this final rule eliminates the requirement that registrants must submit the original certificate of registration or a certified copy thereof with a request for amendment, correction, or surrender of a registration, this final rule will lessen the financial burden on many registrants. In situations where a registrant does not have a certified copy of his or her own registration, the

registrant, whether a large or small entity, will no longer be required to pay fees to the USPTO to obtain a certified copy of his or her own registration.

Accordingly, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the rule changes will not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)).

Executive Order 13132

This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866

This rule making has been determined not to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information and recordkeeping requirements have been reviewed and approved by OMB under OMB Control Number 0651-0009, Trademark Processing. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 2

Administrative practice and procedure, Trademarks.

■ For the reasons given in the preamble and under the authority contained in 35 U.S.C. 2 and 15 U.S.C. 1123, as amended, the Office amends part 2 of title 37 as follows:

■ 1. The authority citation for 37 CFR Part 2 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 2. Revise § 2.172 to read as follows:

§ 2.172 Surrender for cancellation.

Upon application by the registrant, the Director may permit any registration to be surrendered for cancellation. An application for surrender must be signed by the registrant. When there is more than one class in a registration, one or

more entire class(es) but less than the total number of classes may be surrendered. Deletion of less than all of the goods or services in a single class constitutes amendment of registration as to that class (*see* § 2.173).

■ 3. Amend § 2.173 by revising paragraph (a) to read as follows:

§ 2.173 Amendment of registration.

(a) A registrant may apply to amend a registration or to disclaim part of the mark in the registration. The registrant must submit a written request specifying the amendment or disclaimer. This request must be signed by the registrant and verified or supported by a declaration under § 2.20, and accompanied by the required fee. If the amendment involves a change in the mark, the registrant must submit a new specimen showing the mark as used on or in connection with the goods or services, and a new drawing of the amended mark. The registration as amended must still contain registrable matter, and the mark as amended must be registrable as a whole. An amendment or disclaimer must not materially alter the character of the mark.

* * * * *

■ 4. Revise § 2.174 to read as follows:

§ 2.174 Correction of Office mistake.

Whenever a material mistake in a registration, incurred through the fault of the United States Patent and Trademark Office, is clearly disclosed by the records of the Office, a certificate of correction stating the fact and nature of the mistake, signed by the Director or by an employee designated by the Director, shall be issued without charge and recorded. A printed copy of the certificate of correction shall be attached to each printed copy of the registration certificate. Thereafter, the corrected certificate shall have the same effect as if it had been originally issued in the corrected form. In the discretion of the Director, the Office may issue a new certificate of registration without charge.

■ 5. Amend § 2.175 by revising paragraphs (a) and (b) to read as follows:

§ 2.175 Correction of mistake by registrant.

(a) Whenever a mistake has been made in a registration and a showing has been made that the mistake occurred in good faith through the fault of the registrant, the Director may issue a certificate of correction. In the discretion of the Director, the Office may issue a new certificate upon payment of the required fee, provided that the correction does not involve

such changes in the registration as to require republication of the mark.

(b) An application for such action must:

(1) Include the following:

(i) Specification of the mistake for which correction is sought;

(ii) Description of the manner in which it arose; and

(iii) A showing that it occurred in good faith;

(2) Be signed by the registrant and verified or include a declaration in accordance with § 2.20; and

(3) Be accompanied by the required fee.

* * * * *

■ 6. Revise § 2.176 to read as follows:

§ 2.176 Consideration of above matters.

The matters in §§ 2.171 to 2.175 will be considered in the first instance by the Post Registration Examiners. If the action of the Examiner is adverse, registrant may petition the Director to review the action under § 2.146. If the registrant does not respond to an adverse action of the Examiner within 6 months of the mailing date, the matter will be considered abandoned.

Dated: August 13, 2004.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 04-19016 Filed 8-18-04; 8:45 am]

BILLING CODE 3510-16-P

POSTAL SERVICE

39 CFR Part 601

Issue 3 of the Purchasing Manual; Incorporation by Reference

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service announces the publication of Issue 3 of the Postal Service Purchasing Manual. Issue 3 supersedes previous editions of the Purchasing Manual, and is incorporated by reference in the Code of Federal Regulations.

EFFECTIVE DATE: This final rule is effective on August 19, 2004. The incorporation by reference of the Purchasing Manual, Issue 3 is approved by the Director of the Federal Register as of August 19, 2004.

FOR FURTHER INFORMATION CONTACT: Michael J. Harris (202) 268-5653.

SUPPLEMENTARY INFORMATION: Issue 1 of the Purchasing Manual was issued on January 31, 1997, as the successor to former USPS Publication 41, the U.S.

and/or intrarectal use containing any protectant identified in § 346.14(a)(1), (2), (4), (5), (6), (7), and (9), and (b)(1), (2), (3), and (4), or any astringent identified in § 346.18(a) and (c). Apply to the affected area up to 6 times daily or after each bowel movement.

(9) For products containing petrolatum or white petrolatum identified in § 346.14(a)(8) and (10). Apply liberally to the affected area as often as necessary.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

[55 FR 31779, Aug. 3, 1990, as amended at 59 FR 28767, June 3, 1994; 64 FR 13295, Mar. 17, 1999]

§ 346.52 Labeling of permitted combinations of anorectal active ingredients.

Indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity established in § 346.50(a). For a combination drug product that does not have an established name, the labeling of the product states the statement of identity established in § 346.50(a).

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of this subpart.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of this subpart.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of this subpart. When the time intervals or age limitations for administration of the individual ingredients differ, the

directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

347.1 Scope.

347.3 Definitions.

Subpart B—Active Ingredients

347.10 Skin protectant active ingredients.

347.12 Astringent active ingredients.

347.20 Permitted combinations of active ingredients.

Subpart C—Labeling

347.50 Labeling of skin protectant drug products.

347.52 Labeling of astringent drug products.

347.60 Labeling of permitted combinations of active ingredients.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 58 FR 54462, Oct. 21, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 347.1 Scope.

(a) An over-the-counter skin protectant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 347.3 Definitions.

As used in this part:

Astringent drug product. A drug product applied to the skin or mucous membranes for a local and limited protein coagulant effect.

Lip protectant drug product. A drug product that temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips; traditionally called "lip balm."

§ 347.10

Poison ivy, oak, sumac dermatitis. An allergic contact dermatitis due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizer.

Skin protectant drug product. A drug product that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces.

[68 FR 33376, June 4, 2003]

Subpart B—Active Ingredients

SOURCE: 68 FR 33377, June 4, 2003, unless otherwise noted.

§ 347.10 Skin protectant active ingredients.

The active ingredients of the product consist of any of the following, within the concentration specified for each ingredient:

- (a) Allantoin, 0.5 to 2 percent.
- (b) Aluminum hydroxide gel, 0.15 to 5 percent.
- (c) Calamine, 1 to 25 percent.
- (d) Cocoa butter, 50 to 100 percent.
- (e) Cod liver oil, 5 to 13.56 percent, in accordance with § 347.20(a)(1) or (a)(2), provided the product is labeled so that the quantity used in a 24-hour period does not exceed 10,000 U.S.P. Units vitamin A and 400 U.S.P. Units cholecalciferol.
- (f) Colloidal oatmeal, 0.007 percent minimum; 0.003 percent minimum in combination with mineral oil in accordance with § 347.20(a)(4).
- (g) Dimethicone, 1 to 30 percent.
- (h) Glycerin, 20 to 45 percent.
- (i) Hard fat, 50 to 100 percent.
- (j) Kaolin, 4 to 20 percent.
- (k) Lanolin, 12.5 to 50 percent.
- (l) Mineral oil, 50 to 100 percent; 30 to 35 percent in combination with colloidal oatmeal in accordance with § 347.20(a)(4).
- (m) Petrolatum, 30 to 100 percent.
- (n) [Reserved]
- (o) Sodium bicarbonate.
- (p) [Reserved]
- (q) Topical starch, 10 to 98 percent.
- (r) White petrolatum, 30 to 100 percent.
- (s) Zinc acetate, 0.1 to 2 percent.
- (t) Zinc carbonate, 0.2 to 2 percent.

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- (u) Zinc oxide, 1 to 25 percent.

§ 347.12 Astringent active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

- (a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).
- (b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).
- (c) Witch hazel.

§ 347.20 Permitted combinations of active ingredients.

(a) *Combinations of skin protectant active ingredients.* (1) Any two or more of the ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § 347.50(b)(1) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(2) Any two or more of the ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § 347.50(b)(2) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(3) Any two or more of the ingredients identified in § 347.10(b), (c), (j), (s), (t), and (u) may be combined provided the combination is labeled according to § 347.50(b)(3) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(4) The ingredients identified in § 347.10(f) and (l) may be combined provided the combination is labeled according to § 347.50(b)(7) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(b) *Combinations of skin protectant and external analgesic active ingredients.* Any one (two when required to be in combination) or more of the active ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined