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DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1779

Rural Housing Service

7 CFR Part 3575

Rural Business—Cooperative Service

Rural Utilities Service

7 CFR Parts 4279 and 4280

Rural Business—Cooperative Service

Rural Housing Service

Rural Utilities Service

7 CFR Part 5001

[FR Doc. E9–3092]

RIN 0570–AA65

Rural Development Guaranteed Loans

AGENCIES: Rural Business—Cooperative Service, Rural Housing Service, Rural Utilities Service, USDA.

ACTION: Interim rule; delay of the effective date.

SUMMARY: Rural Development is further delaying the effective date of the interim rule for Rural Development Guaranteed Loans, which was published on December 17, 2008, to June 1, 2009. The interim rule establishes a unified guaranteed loan platform for the enhanced delivery of four existing Rural Development guaranteed loan programs—Community Facility; Water and Waste Disposal; Business and Industry; and Rural Energy for America Program, formerly known as Renewable Energy Systems and Energy Efficiency Improvement Projects.

DATES: The effective date of the interim rule, which was published on December 17, 2008 [73 FR 76698], delayed until February 17, 2008 [74 FR 2823], delayed until March 9, 2009 [74 FR 7179], is further delayed until June 1, 2009.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Foore, Rural Development, Business and Cooperative Programs, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Stop 3201, Washington, DC 20250–3201; e-mail: *Michael.Foore@wdc.usda.gov*; telephone (202) 690–4730.

SUPPLEMENTARY INFORMATION: On January 16, 2009, Rural Development delayed the original effective date of the interim rule from January 16, 2009, to February 17, 2009, because there was insufficient time to correct a technical error in the interim rule before the interim rule became effective on January 16, 2009.

Subsequently, Rural Development again delayed the effective date of the interim rule from February 17, 2009, to March 9, 2009 [74 FR 7179, February 13, 2009] allowing for public comments to extend the effective date to June 1, 2009. As stated in the **Federal Register**, Rural Development identified several administrative actions, including providing the best guidance to its field staff on the interim rule, it believed were necessary to occur prior to the February 17, 2009, effective date in order to ensure the successful implementation of the interim rule. Consequently, Rural Development determined that it was necessary to extend the effective date to June 1, 2009, in order to provide Rural Development the necessary time to implement these administrative actions.

As noted in the February 13, 2009, **Federal Register**, Rural Development made this change to the effective date, as is provided for under the Administrative Procedures Act (5 U.S.C. 553(b)(3)(B)), because:

1. Implementing the interim rule on February 17, 2009, would have created substantial legal and operation risks to the affected programs because the rule contains certain flaws that must be corrected and would not have provided the Agency sufficient time to properly train field staff and make changes to IT systems critical to the implementation of these programs. These actions could not have been completed by February 17, 2009.

2. The two week extension would allow the public a reasonable opportunity to comment on this proposed extension of the effective date to June 1, 2009, and the Agency to consider such comments before making the decision to make such extension.

3. Extending the effective date to June 1, 2009, allows the Agency to finish the 60-day review described in the January 20, 2009, memo from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review.''

The public comment period on the Agency's proposed June 1, 2009, effective date closed on February 20, 2009. The Agency received three comment letters on the proposed extension of the effective date. None of the commenters suggested that the interim rule become effective prior to June 1, 2009. Two of the three commenters also submitted comments during the public comment period on the interim rule. Because the comments submitted by these commenters, address issues that are very similar to those included in comments submitted during the public comment period for the interim rule, the Agency will consider these issues when it considers the comments on the interim rule. Therefore, the effective of the interim rule is extended to June 1, 2009.

Dated: March 3, 2009.

William F. Hagy III,

Acting Deputy Under Secretary, Rural Development.

[FR Doc. E9–4839 Filed 3–5–09; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 347

[Docket No. FDA–1978N–0007] (Formerly Docket No. 78N–021A)

RIN 0910–AF42

Astringent Drug Products That Produce Aluminum Acetate; Skin Protectant Drug Products for Over-the-Counter Human Use; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: We (Food and Drug Administration (FDA)) are amending the final monograph (FM) for over-the-counter (OTC) skin protectant astringent drug products. This amendment clarifies that aluminum acetate solutions, produced by dissolving aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder or tablet form in water, are generally recognized as safe and effective (GRASE) and not misbranded as astringent drug products. The amendment also describes how manufacturers should relabel these products to comply with the FM. We are issuing this amendment in response to a citizen petition (CP) that we received from a manufacturer of OTC astringent drug products. This final rule is part of our ongoing review of OTC drug products.

DATES: *Effective Date*: This regulation is effective March 6, 2009.

Compliance Date: The compliance date for all products, regardless of annual sales, is September 6, 2010.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. What Is the Regulatory History of This Rulemaking?

A. Advance Notice of Proposed Rulemaking (ANPR)

We published an ANPR for certain OTC skin protectant drug products in the **Federal Register** on September 7, 1982 (47 FR 39436) (the 1982 ANPR). In the 1982 ANPR, the agency reported that the Advisory Review Panel on OTC Miscellaneous External Drug Products (the Panel) recommended that we classify solutions containing 2.5 to 5 percent aluminum acetate as GRASE for topical use as an astringent. The 1982 ANPR includes the following terms when referring to this ingredient (47 FR 39436 at 39444 through 39446):

- ''aluminum acetate''
- ''aluminum acetate solution''
- ''Burow's solution''

Although some of the aluminum acetate products that the Panel evaluated were powders and tablets that were dissolved in water (Refs. 1 and 2), those products, as manufactured, did not contain aluminum acetate. Rather, those powders and tablets contained aluminum sulfate and calcium acetate, which produced an aluminum acetate solution when dissolved in water.

In addition, the Panel separately evaluated aluminum sulfate and calcium acetate as OTC astringent single active ingredients (i.e., when not in combination with each other). The Panel recommended that aluminum sulfate, as a single active ingredient, is GRASE and not misbranded only for use in a styptic pencil (47 FR 39436 at 39447 and 39448).[1] The Panel recommended that calcium acetate be classified as not GRASE or misbranded when used as a single active ingredient (47 FR 39436 at 39444). The Panel was not aware of any data demonstrating the safety and effectiveness of calcium acetate, as a single active ingredient, when used as an OTC astringent active ingredient in any formulation.

B. Proposed Rule

In the **Federal Register** of April 3, 1989 (54 FR 13490), we published a proposed rule amending the tentative final monograph (TFM) for OTC skin protectant drug products to include astringent drug products (the 1989 TFM). In the 1989 TFM, we proposed monograph status for aluminum acetate, as recommended by the Panel (54 FR 13490 at 13494). However, we revised the Panel's recommended concentration to 0.13 to 0.5 percent, indicating that the Panel did not take into account further dilution of the 2.5 to 5 percent aluminum acetate solution (54 FR 13490 at 13494 and 13496). We agreed with the Panel's recommendation for calcium acetate and proposed that the ingredient be classified as nonmonograph (54 FR 13490 at 13496). We also noted that one comment mentioned that the USP (United States Pharmacopeia) procedure for preparing Burow's Solution (aluminum acetate solution) de novo does not pertain to modified aluminum acetate solutions prepared from tablets or powders (54 FR 13490 at 13494).

C. Final Rule

In the **Federal Register** of October 21, 1993 (58 FR 54458), we published a final rule in the form of a FM for OTC skin protectant drug products that established conditions under which OTC astringent drug products are GRASE and not misbranded (the 1993 skin protectant FM). The 1993 skin protectant FM added GRASE astringent active ingredients and labeling for astringents to 21 CFR part 347 subpart A. The 1993 skin protectant FM, which became effective on October 21, 1994, includes 0.13 to 0.5 percent aluminum acetate as an active ingredient in § 347.12 (21 CFR 347.12) (then § 347.10(a) (21 CFR 347.10(a))). The 1993 skin protectant FM specifies that, 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 consumers contains 0.13 to 0.5 percent aluminum acetate.

In the 1993 skin protectant FM, we noted that calcium acetate was listed in § 310.545(a)(18)(ii) (21 CFR 310.545(a)(18)(ii)) as nonmonograph in a final rule published on May 10, 1993 (58 FR 27636 at 27642).

D. Feedback Letter

A manufacturer submitted a letter in 1994 requesting clarification whether its OTC astringent drug product, a powder containing aluminum sulfate and calcium acetate, could continue to be marketed under the 1993 skin protectant FM (Ref. 3). The manufacturer stated that it markets one of the products reviewed by the Panel in which aluminum acetate was determined to be GRASE for OTC astringent drug products. When dissolved in water according to labeled directions, the manufacturer's product becomes an aluminum acetate solution with a calcium sulfate precipitate.

In a 1995 letter to the manufacturer, we stated that the product fails to comply with the 1993 skin protectant FM because it contains the nonmonograph ingredient calcium acetate (Ref. 4). We suggested that the manufacturer contact us to amend the 1993 skin protectant FM to allow continued marketing of its product. Subsequently, the manufacturer submitted a CP (Ref. 5).

II. Why Is FDA Issuing This Document?

We are issuing this technical amendment in response to the CP submitted by an OTC astringent drug product manufacturer in 1995 (the 1995 CP) (Ref. 5). The 1995 CP was submitted by a manufacturer who marketed one of the products reviewed by the Panel in which aluminum acetate was determined to be GRASE for OTC astringent drug products (see section I.D of this document). The 1995 CP requested that we revise the skin protectant FM (§ 347.12(a) (then § 347.10(a)) as follows, or in equivalent language having the same effect (Ref. 5): ''Aluminum acetate, 0.13 to 0.5 percent

[1] In the 1982 ANPR, we stated that the Panel had concluded that aluminum sulfate is safe but that there were insufficient data to establish its effectiveness for use as a styptic pencil (47 FR 39436 at 39447 and 39448). In the **Federal Register** of April 3, 1989 (54 FR 13490 at 13493), we stated that an apparent administrative error had occurred in that the Panel had voted to classify aluminum sulfate as GRASE and not misbranded for use in a styptic pencil.

(where the product as marketed consists of salts other than aluminum acetate, or where the aluminum acetate concentration of the product as marketed is other than 0.13 to 0.5 percent, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer consists of 0.13 to 0.5 percent aluminum acetate).'' The manufacturer intended ''salts other than aluminum acetate'' to include dry formulations of aluminum sulfate plus calcium acetate. The manufacturer argued that its labeled directions produce an aluminum acetate solution that falls within the concentration range specified in the 1993 skin protectant FM.

We have not taken any enforcement action against these powder and tablet products that produce an aluminum acetate solution while developing this document as our response to the 1995 CP. In this document, we are granting the request in the 1995 CP to revise the 1993 skin protectant FM by including the combination of aluminum sulfate and calcium acetate in powder and tablet dosage forms to prepare an aluminum acetate solution.

III. What Changes to the Skin Protectant FM Is FDA Making in This Document?

This document adds the GRASE combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder or tablet form to produce a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the volume of water specified in ''Directions.'' This technical amendment also includes additional labeling requirements for OTC astringent drug products that consist of this GRASE combination of active ingredients.

Since we issued the 1993 skin protectant FM, the *United States Pharmacopeia/National Formulary* (USP/NF) has added monographs for

- Aluminum Sulfate and Calcium Acetate Tablets for Topical Solution (Ref. 6) and
- Aluminum Sulfate and Calcium Acetate for Topical Solution (Ref. 7).

The second USP monograph is for products formulated as powders. The USP monographs state that these products contain aluminum sulfate tetradecahydrate and calcium acetate monohydrate, which are the hydrate forms of aluminum sulfate and calcium acetate. When a tablet or powder containing the aluminum sulfate tetradecahydrate and calcium acetate monohydrate is dissolved in water, a chemical reaction occurs that produces an aluminum acetate solution and a calcium sulfate precipitate.

Rather than amend the aluminum acetate section of the 1993 skin protectant FM as requested in the 1995 CP, we are redesignating existing § 347.20(b) as § 347.20(c), and adding a new § 347.20(b), to include the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder and tablet dosage forms to prepare an aluminum acetate solution. We are limiting the combination of ingredients to powder and tablet dosage forms because there are corresponding USP monographs for these dosage forms, but not for other dosage forms (Refs. 6 and 7). New § 347.20(b) states:''*Combination of ingredients to prepare an aluminum acetate solution.* Aluminum sulfate tetradecahydrate may be combined with calcium acetate monohydrate in powder or tablet form to provide a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the volume of water specified in 'Directions'.'' This amendment provides an alternate approach to prepare the aluminum acetate solution described in § 347.12(a).

Marketed products have contained varying amounts of aluminum sulfate and calcium acetate based on the amount of water in which the powder or tablet is dissolved to make an aluminum acetate solution. For example, a product with directions to use 16 ounces of water requires a larger amount of each ingredient than a product with directions to use 12 ounces of water. Generally, the products have contained between 53 and 59 percent aluminum sulfate and 40 to 44 percent calcium acetate in each tablet or powder. Inactive ingredients account for the other amounts to make 100 percent.

Because of the varying amount of aluminum sulfate and calcium acetate, we are not specifying an amount for each active ingredient required in a product. However, this information is required to appear in the product's labeling (see 21 U.S.C. 352(e)(1)(A)(ii) and § 201.66(c)(2) (21 CFR 201.66(c)(2))). Labeling must state the amount of each active ingredient in the product and those amounts, when dissolved in the amount of water stated in the product's labeling, must produce a 0.13 to 0.5 percent aluminum acetate solution. We are providing labeling in this document to allow manufacturers to continue to market these products in this manner.

We are revising § 347.52 (*Labeling of astringent drug products*) (21 CFR 347.52), which describes specific labeling for products containing aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder or tablet dosage forms (see *Sample OTC Astringent Drug Product Label*). ''Aluminum sulfate tetradecahydrate'' and ''calcium acetate monohydrate'' must appear under the ''Active ingredients'' heading in Drug Facts, as is typical for OTC drug products. Under the ''Purpose'' heading, an asterisk should follow the word ''Astringent''. In addition, a statement explaining the asterisk should be included in the ''Active ingredients/Purpose'' section: ''*When combined together in water, these ingredients form the active ingredient aluminum acetate. See **Directions**.'' The ''Directions'' section should include instructions on preparing the aluminum acetate solution (0.13 to 0.5 percent) from the powder(s) or tablet(s). These directions will inform consumers that a solution is produced by dissolving the powder(s) or tablet(s) in water. We believe this labeling in the ''Active ingredients/Purpose'' and ''Directions'' sections adequately informs consumers that aqueous aluminum acetate is acting as the astringent active ingredient.

The combination product containing aluminum sulfate tetradecahydrate and calcium acetate monohydrate has the same indications and warnings as other monograph astringent products containing aluminum acetate. We are requiring that the ''for use as a soak'' and ''for use as a compress or wet dressing'' subheadings in the ''Directions'' section appear in bold type to make it easier for consumers to read and follow the different parts of the directions for these products (see *Sample OTC Astringent Drug Product Label*). For consistency in labeling, we are also requiring that the same two subheadings in the ''Directions'' section of OTC aluminum acetate solution drug products described in § 347.12(a) appear in bold type. The information under these subheadings for both types of aluminum acetate drug products (i.e., dry and solution formulations) is still required to appear in a bulleted format (see § 347.52(d)(1)(i) and (d)(1)(ii)).

The following sample OTC astringent drug product label illustrates the labeling for products containing aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder or tablet dosage forms to produce an aluminum acetate solution:

BILLING CODE 4160–01–S

Drug Facts

Active ingredients (in each packet)	Purpose
Aluminum sulfate tetradecahydrate, xxx mg	Astringent*
Calcium acetate monohydrate, xxx mg	Astringent*

* When combined together in water, these ingredients form the active ingredient aluminum acetate. See ***Directions***.

Use

- For temporary relief of minor skin irritations due to insect bites

Warnings

For external use only

When using this product

- avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- do not cover compress or wet dressing with plastic to prevent evaporation
- in some skin conditions, soaking too long may overdry

Stop use and ask a doctor if

- condition worsens or symptoms last more than 7 days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- dissolve 1 to 3 packets in a pint (16 oz) of cool or warm water
- stir until fully dissolved; do not strain or filter. The resulting mixture contains 0.15% (1 packet), 0.30% (2 packets), or 0.45% (3 packets) aluminum acetate and is ready for use.

For use as a soak:

- soak affected area for 15 to 30 minutes as needed, or as directed by a doctor
- repeat 3 times a day or as directed by a doctor
- discard solution after each use

For use as a compress or wet dressing:

- soak a clean, soft cloth in the solution
- apply cloth loosely to affected area for 15 to 30 minutes
- repeat as needed or as directed by a doctor
- discard solution after each use

Inactive ingredients XXXXXXXXXXXXX

Questions or comments? call toll free 1-800-XXX-XXXX

BILLING CODE 4160–01–C

This sample label includes the specific labeling required for these products in this technical amendment as well as the general labeling required by the 1993 skin protectant FM. The format and sequence of the information and the font sizes for the title, heading, subheadings, text, and other graphic features must be in accordance with § 201.66.

In addition to adding new § 347.20(b), we are revising § 310.545(a)(18)(ii), which currently lists calcium acetate as a nonmonograph active ingredient that cannot be included in OTC astringent drug products. That section now reads as follows: ''Calcium acetate (except calcium acetate monohydrate when combined with aluminum sulfate tetradecahydrate to provide an aluminum acetate solution as described in § 347.20(b)).'' Therefore, calcium acetate is still nonmonograph except in products marketed under new § 347.20(b).

Because this document adds new § 347.20(b), we are redesignating existing § 347.20(b), (c), and (d) as § 347.20(c), (d), and (e), respectively. We are also revising the warnings in 21 CFR 347.50(c) to reflect the Drug Facts format in § 201.66, while not changing the meaning of these warnings. The *Sample OTC Astringent Drug Product Label* reflects all of these revisions.

IV. Analysis of Impacts

We have examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We conclude that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because only a limited number of products will need to be relabeled, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to amend the 1993 skin protectant FM to add the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate for products that include appropriate amounts of these ingredients and adequate directions to produce an aluminum acetate solution within the monograph concentration range. This amendment describes a methodology for manufacturers of these OTC astringent drug products to relabel their products and market them in compliance with the 1993 skin protectant FM.

We have identified two OTC skin protectant astringent drug products, each with several stockkeeping units (SKUs) (individual products, packages, and sizes), that may need to be relabeled. While we are aware of several other products that are no longer marketed, there may be a few marketed products of which we are not currently aware. Accordingly, we estimate that there may be 5 products with 5 to 10 SKUs that may be affected by this final rule.

We have updated the weighted average cost to relabel that we estimated for the final rule requiring uniform label formats of OTC drug products (64 FR 13254 at 13279 to 13281, March 17, 1999) (i.e., $3,600 x 1.164[2] = $4,190 per SKU). Assuming up to 10 affected OTC SKUs in the marketplace, total one-time costs of relabeling could be $41,900 (i.e., 10 x $4,190). Because frequent labeling redesigns are a recognized cost of doing business in the OTC drug industry, these costs may be less. Manufacturers that make voluntary market-driven changes to their labeling during the implementation period can implement the regulatory requirements for a nominal cost. All products, including those with annual sales less than $25,000, will have 18 months following publication of the final rule to comply with the 1993 skin protectant FM. Therefore, many of the labeling revisions may be done in the normal course of business. These steps should help to minimize the impact on small entities by providing enough time for implementation to enable entities to use up existing labeling stock. In addition, the final rule does not require any new reporting or recordkeeping activities.

This final rule also requires manufacturers of the aluminum acetate solution products described in § 347.12(a) to make two very minor changes in the labeling of their products. They will need to change the two ''for use'' subheadings in the directions from standard to bold type and should be able to do so at a negligible cost. We estimate that less than 10 SKUs will be affected by this minor change. This final rule will not impose a significant economic burden on affected entities. Therefore, we certify that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

[2] The annual PPI for pulp, paper, and allied products (the major cost driver for labeling) rose from 174.1 to 202.6 between 1998 and 2005 (see *http://data.bls.gov/cgi-bin/surveymost*). We have verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

V. Paperwork Reduction Act of 1995

We conclude that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule will have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress

intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 751 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379r) is an express preemption provision. Section 751(a) of the act (21 U.S.C. 379r(a)) provides that: ''* * * no State or political subdivision of a State may establish or continue in effect any requirement—* * * (1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 *et seq.*), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*).''

Currently, this provision operates to preempt States from imposing requirements related to the regulation of nonprescription drug products. (See section 751(b) through (e) of the act for the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.) This final rule clarifies that OTC astringent drug products containing aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder or tablet form for dissolving in water to produce an aluminum acetate solution are GRASE and not misbranded. The final rule also describes how manufacturers should relabel these products to comply with the 1993 skin protectant FM. Although this final rule would have a preemptive effect, in that it would preclude States from issuing requirements related to these OTC astringent drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule, this preemptive effect is consistent with what Congress set forth in section 751 of the act. Section 751(a) of the act displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision is not applicable, implied preemption may arise. See *Geier* v. *American Honda Co.*, 529 U.S. 861 (2000).

We believe that the preemptive effect of the final rule would be consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' We provided the States with an opportunity for appropriate participation in this rulemaking when we sought input from all stakeholders through publication of the 1993 skin protectant FM. We received no comments from any States on the final rulemaking.

In addition, on December 17, 2008, FDA's Division of Federal and State Relations provided notice via fax and e-mail transmission to elected officials of State governments and their representatives of national organizations. The notice provided the States with further opportunity for input on the rule. It advised the States of the publication of the final rule and encouraged State and local governments to review the notice and to provide any comments to the docket (Docket No. 1978N–0021A), by a date 30 days from the date of the notice (i.e., by January 16, 2009), or to contact certain named individuals. We did not receive any comments in response to this notice. The notice has been filed in the above-numbered docket.

In conclusion, we believe that we have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VIII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under Docket No. FDA–1978N–0007 (formerly Docket No. 1978N–021A) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bluboro product label, Appendix A to CP1.

2. Domeboro product label.

3. Letter from S. Buxbaum, Allergan, to R. Heller, FDA, dated January 24, 1994, Appendix C to CP1.

4. Letter from B. Williams, FDA, to T. Mead, Allergan, dated January 2, 1995, Appendix D to CP1.

5. CP1.

6. *The United States Pharmacopeia 31-National Formulary 26*, The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 1360, 2008.

7. *The United States Pharmacopeia 31-National Formulary 26*, The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1359, 2008.

List of Subjects

21 CFR Part 310

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

21 CFR Part 347

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310 and 347 are 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 the entry for calcium acetate in paragraph (a)(18)(ii), by revising paragraph (d) introductory text and paragraph (d)(11), and by adding new paragraph (d)(39) to read as follows:

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

(a) * * *

(18) * * *

(ii) * * *

*	*	*	*	*

Calcium acetate (except calcium acetate monohydrate when combined with aluminum sulfate tetradecahydrate to provide an aluminum acetate solution as described in § 347.20(b)) of this chapter

*	*	*	*	*

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(39) of this section.

*	*	*	*	*

(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 and except products that contain calcium acetate monohydrate as covered by paragraph (d)(39) 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.

*	*	*	*	*

(39) September 6, 2010, for products subject to paragraph (a)(18)(ii) of this section that contain calcium acetate monohydrate, except as provided in § 347.20(b) of this chapter.

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

■ 3. The authority citation for 21 CFR part 347 continues to read as follows:

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

■ 4. Section 347.20 is amended by redesignating paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e), respectively, and by adding new paragraph (b) to read as follows:

§ 347.20 Permitted combinations of active ingredients.

* * * * *

(b) *Combination of ingredients to prepare an aluminum acetate solution.* Aluminum sulfate tetradecahydrate may be combined with calcium acetate monohydrate in powder or tablet form to provide a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the volume of water specified in ''Directions.''

* * * * *

■ 5. Section 347.52 is amended by revising paragraph (a) and (b)(1) paragraph heading, and by revising paragraphs (c) and (d)(1), and by adding new paragraph (d)(4) to read as follows:

§ 347.52 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''astringent.'' *For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*, under the ''Purpose'' heading identified in § 201.66(c)(3) of this chapter, the labeling of each active ingredient in the product states ''Astringent*'', which is followed by the statements ''* When combined together in water, these ingredients form the active ingredient aluminum acetate. See [the following in bold italic type] Directions.''

(b) *Indications.* * * *

(1) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b).* * * *

* * * * *

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For all products*—(i) The labeling states ''For external use only''.

(ii) The labeling states ''When using this product [bullet] avoid contact with eyes. If contact occurs, rinse thoroughly with water.''

(2) *For products containing aluminum acetate identified in § 347.12(a), witch hazel identified in § 347.12(c), or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b).* The labeling states ''Stop use and ask a doctor if [bullet] condition worsens or symptoms last more than 7 days''.

(3) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b) when labeled for use as a compress or wet dressing.* The labeling states ''When using this product [bullet] do not cover compress or wet dressing with plastic to prevent evaporation''.

(4) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b) when labeled for use as a soak, compress, or wet dressing.* The labeling states ''When using this product [bullet] in some skin conditions, soaking too long may overdry''.

(d) *Directions.* * * *

(1) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*—(i) *For products used as a soak.* ''For use as a soak: [preceding words in bold type] [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use'' .

(ii) *For products used as a compress or wet dressing.* ''For use as a compress or wet dressing: [preceding words in bold type] [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use''.

* * * * *

(4) *For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*—(i) *For powder dosage form.* The labeling states ''[bullet] dissolve 1 to 3 packets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 packet), [insert percent] (2 packets), or [insert percent] (3 packets) aluminum acetate and is ready for use.'' These statements shall be the first statements under the heading ''Directions''.

(ii) *For tablet dosage form.* The labeling states ''[bullet] dissolve 1 to 3 tablets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 tablet), [insert percent] (2 tablets), or [insert percent] (3 tablets) aluminum acetate and is ready for use.'' These statements shall be the first statements under the heading ''Directions''.

* * * * *

Dated: February 23, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4746 Filed 3–5–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2009–N–0099]

New Drug Applications and Abbreviated New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its new drug application (NDA) and abbreviated new drug application (ANDA) regulations to update agency contacts for patent information and patent notifications and to correct an inaccurate cross-reference. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective March 6, 2009.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3506.

SUPPLEMENTARY INFORMATION: FDA is amending its NDA and ANDA regulations in part 314 (21 CFR part 314) to update agency contacts for information and notifications pertaining to patents and to correct an inaccurate reference. To accommodate the ongoing relocation of FDA offices, users are directed to FDA's Web site to obtain the current address of the Office of Generic Drugs.

In §§ 314.52(a)(2) and 314.95(a)(2), FDA is updating the agency contact for obtaining the name and address of the NDA holder or designee for purposes of providing notice of a patent certification submitted under section 505(b)(2)(A)(iv)