Commission's EDGAR system or who submits funds to the U.S. Treasury designated depository in anticipation of paying a filing fee. Account statements are regularly prepared and provided to account holders. Account holders must maintain a current account address with the Commission to ensure timely access to these statements.

Note to paragraph (d). The deposit of money into a filing fee account does not constitute payment of a filing fee. Payment of the filing fee occurs at the time the filing is made, commensurate with the drawing down of the balance of the fee account.

(e) *Return of funds from inactive accounts.* Funds held in any filing fee account in which there has not been a deposit, withdrawal or other adjustment for more than 180 calendar days will be returned to the account holder, and account statements will not be sent again until a deposit, withdrawal or other adjustment is made with respect to the account. Filers must maintain a current account address to assure the timely return of funds. It may not be possible to return funds from inactive accounts if the Commission is unable to identify a current account address of an account holder after making reasonable efforts to do so.

Note to paragraph (e). A company must update its account and other addresses using the EDGAR Web site. This method ensures data integrity and the timeliest update. Simply changing an address in the text of the cover page of a filing made on the EDGAR system will not be sufficient to update the Commission's account address records.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l*, 78m, 78n, 78o, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

■ 4. Section 230.111 is revised to read as follows:

§ 230.111 Payment of fees.

All payments of fees for registration statements under the Act shall be made by wire transfer, or by certified check, bank cashier's check, United States postal money order, or bank money order payable to the Securities and Exchange Commission, omitting the name or title of any official of the Commission. There will be no refunds. Payment of fees required by this section shall be made in accordance with the directions set forth in § 202.3a of this chapter.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 5. The authority citation for part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 6. Section. 240.0–9 is revised to read as follows:

§ 240.0–9 Payment of fees.

All payment of fees shall be made by wire transfer, or by certified check, bank cashier's check, United States postal money order, or bank money order payable to the Securities and Exchange Commission, omitting the name or title of any official of the Commission. Payment of filing fees required by this section shall be made in accordance with the directions set forth in § 202.3a of this chapter.

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

■ 7. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 77sss, 78*ll*(d), 80b–3, 80b–4, and 80b–11.

§ 260.7a–10 [Removed]

■ 8. Section 260.7a–10 is removed.

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 9. The authority citation for part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, and 80a–39, unless otherwise noted.

* * * * *

■ 10. Section 270.0–8 is revised to read as follows:

§ 270.0–8 Payment of fees.

All payment of fees shall be made by wire transfer, or by certified check, bank cashier's check, United States postal money order, or bank money order payable to the Securities and Exchange Commission, omitting the name or title of any official of the Commission. Payment of fees required by this section shall be made in accordance with the directions set forth in § 202.3a of this chapter.

By the Commission.

Dated: January 29, 2008.

Nancy M. Morris,

Secretary.

[FR Doc. E8–1839 Filed 1–31–08; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket Nos. 1978N–0021 and 1978N–0021P] (formerly Docket Nos. 78N–0021 and 78N–0021P)

RIN 0910–AF42

Skin Protectant Drug Products for Over-the-Counter Human Use; Reduced Labeling; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that establishes conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective (GRASE) and not misbranded. This amendment revises labeling requirements for OTC skin protectant drug products formulated and marketed as lip protectants.

DATES: This rule is effective March 3, 2008.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Why Are We Publishing This Document?

This document addresses submissions that FDA received in response to a June 4, 2003, final rule for OTC skin protectant drug products (68 FR 33362). The final rule establishes reduced labeling requirements for the following products (68 FR 33362 at 33374):

- products formulated and labeled as lip protectants that meet the criteria established in § 201.66(d)(10) (21 CFR 201.66(d)(10)) (§ 347.50(e));
- products containing only cocoa butter, petrolatum, or white petrolatum

identified in § 347.10(d), (m), and (r), used singly or in combination with each other, and marketed other than as a lip protectant (§ 347.50(f));

- sunscreen drug products labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and around the eyes) and that meet the criteria established in § 201.66(d)(10) (§ 352.52(f)); and
- products containing combinations of skin protectant and sunscreen active ingredients (§ 352.60(b)(2), (c), and (d)).

Because we had not previously proposed this reduced labeling, we requested comments specifically on these new labeling requirements. This document addresses the five issues presented in the three sets of comments that we received after the final rule. All of the comments request changes to existing regulatory requirements. As explained in section II of this document, we agree to make the changes requested in two of the comments and are, therefore, amending the final rule to:

- add an alternative statement of identity for skin protectant products formulated and marketed as lip protectants and
- allow omission of a warning for lip protectant products that meet the criteria established in § 201.66(d)(10).

As also explained in section II of this document, we do not agree to make the other three changes requested in the submissions.

II. What Are Our Conclusions on the Submissions?

(Comment 1) A drug manufacturer requested that we include the term ''lip protectant'' as an alternative statement of identity for skin protectants marketed as lip protectants (Ref. 1). The manufacturer notes that we have distinctly identified products formulated and marketed as lip protectants in other areas of the skin protectant final rule, including §§ 347.3 and 347.50(b)(2)(ii), (e), and (f). The manufacturer further points out that we have permitted a product used to treat poison ivy, oak, and sumac to be distinctly identified as a ''poison ivy, oak, sumac protectant'' in § 347.50(a)(3).

We agree with the manufacturer and are including the term ''lip protectant'' as an alternative statement of identity for skin protectant drug products formulated and marketed as lip protectants. We agree that the term ''lip protectant'' accurately describes this category of products and is readily understood by consumers. Accordingly, we are adding the following new paragraph in § 347.50(a): *For any product formulated as a lip protectant.* ''Skin protectant,'' ''lip protectant,'' or ''lip balm'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(Comment 2) A drug manufacturer requested that we allow reduced labeling for all lip protectant products, whether or not they meet the criteria established in § 201.66(d)(10) (i.e., whether or not they are sold in small packages) (Ref. 1). The manufacturer states that the skin protectant final rule (68 FR 33362 at 33380 to 33381) amends the final rule for OTC sunscreen drug products to allow reduced labeling ''without the need to meet the criteria established in § 201.66(d)(10)'' for the following products:

- Sunscreen products that are marketed as lip protectants or lipsticks (§ 352.52(c)(2) and (d)(4)) and
- Combination sunscreen-skin protectant drug products marketed as lip protectants or lipsticks (§ 352.60(c) and (d)).

Because the skin protectant monograph (§ 347.50(e)) allows reduced labeling only for lip protectants that meet the criteria in § 201.66(d)(10), the manufacturer argues that the skin protectant and sunscreen monographs are inconsistent.

We have determined that the reduced labeling requirements established under § 347.50(e) for OTC lip protectant products are appropriate only if the criteria of § 201.66(d)(10) are met. If the criteria of § 201.66(d)(10) are not met, at least one of the factors upon which we relied to conclude that minimal information is needed for safe and effective use of lip protectants would not apply, namely, the product would not necessarily be sold in small packages (see 68 FR 33362 at 33371). Further, if the § 201.66(d)(10) criteria are not met, space constraints would not exist to support reduced labeling. We believe the current labeling requirements for lip protectant products that do not satisfy the § 201.66(d)(10) criteria benefit consumers and should continue to apply.

Therefore, we are not revising the criteria for reduced labeling in the skin protectant monograph. We will address, in a separate rulemaking for the sunscreen monograph, whether sunscreen lip protectant products (i.e., sunscreen products marketed as lip protectants or combination sunscreen-skin protectant drug products marketed as lip protectants or lipsticks) should also be required to satisfy the conditions of § 201.66(d)(10) in order to qualify for reduced labeling requirements. We intend to publish a sunscreen rulemaking in a future issue of the **Federal Register**. The rulemaking will address various labeling and testing requirements for both ultraviolet A (UVA) and ultraviolet B (UVB) rays, including reduced labeling requirements for sunscreen lip protectant products.

(Comment 3) A drug manufacturer argued that the warning statement exemption allowed for sunscreens combined with skin protectants (§ 352.60(c)) should be extended to all lip protectant products (Ref. 1). Section 352.60(c) of the sunscreen monograph permits sunscreen-skin protectant combinations to omit the warning in § 347.50(c)(3): ''Stop use and ask a doctor if [bullet] condition worsens [bullet] symptoms last more than 7 days or clear up and occur again within a few days.'' The manufacturer points out that the skin protectant monograph does not allow this warning to be omitted for skin protectants formulated and labeled as lip protectants. Section 347.50(e)(1)(iii) of the skin protectant monograph allows the warning to be shortened (i.e., ''Stop use and ask a doctor if condition lasts more than 7 days'') but not omitted. The manufacturer argues that the requirement for this warning makes the skin protectant and sunscreen monographs inconsistent.

We agree with the manufacturer and are changing the skin protectant monograph to allow the warning to be omitted for lip protectant products that meet the requirements in § 201.66(d)(10). In the preamble to the skin protectant final rule, we concluded that minimal information is needed for safe and effective use of lip protectant products because of specific characteristics of these products (68 FR 33362 at 33371), including that they:

- are typically packaged in small amounts,
- are applied to limited areas of the body,
- have high therapeutic index,
- are extremely low risk in consumer use situations,
- provide a favorable public health benefit,
- require no specified dosage limitation, and
- require few specific warnings and no general warnings.

Because minimal information is needed for their safe and effective use, we agree that lip protectant products meeting the criteria in § 201.66(d)(10) can be exempted from the 7-day warning requirement otherwise applicable to skin protectants under § 347.50(c)(3). We believe consumers can safely and effectively use these products without this warning. Accordingly, we are revising § 347.50(e)(1)(iii) in the skin protectant monograph to read: ''The

'external use only' warning in § 347.50(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The warnings in § 347.50(c)(2), (c)(3), and (c)(4) are not required.'' This revision will make the skin protectant and sunscreen monographs consistent in this regard, as requested by the manufacturer.

(Comment 4) A law firm requested that we allow additional reduced labeling for lip protectants and all other skin protectant drug products by eliminating the requirement to list the established name of an active ingredient both on the principal display panel (PDP) and in the Drug Facts box (Ref. 2). The law firm argues that the PDP for skin protectants and, in fact, most OTC drug products should only include the general pharmacological category as the statement of identity.

The issue raised by the law firm is outside the scope of the reduced labeling issues for which we sought comments in the skin protectant final rule. We do not believe it appropriate to address this issue in this document because the issue impacts the labeling for all OTC drug products. The law firm, or any other party interested in amending the OTC labeling regulations, can submit a citizen petition in accordance with 21 CFR 10.30.

(Comment 5) A drug manufacturers' association requested that we consider a greater degree of flexibility in the reduced labeling allowed for skin protectant (lip protectant) and skin protectant-sunscreen combination products (Ref. 3). Specifically, the association asks that we permit manufacturers to list inactive ingredients somewhere other than on the container label for ''products such as lip balms and lip balms with sunscreen,'' which are sold in very small containers similar to lipsticks containing sunscreens. The association notes that we permit this labeling exception for some cosmetic products.

We are denying the request to list inactive ingredients somewhere other than on the container label for skin protectant and skin protectant-sunscreen combination drug products. We do allow listing of inactive ingredients for some cosmetic products in labeling accompanying the product rather than on the container label (21 CFR 701.3(i)). However, we do not allow inactive ingredients to be listed somewhere other than on the container label if the cosmetic product is also a drug product (e.g., a lipstick containing sunscreen).

Section 502(e)(1)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(e)(1)(A)(iii)) requires that the inactive ingredients of a drug be listed on the outside of the retail package and, if determined to be appropriate by FDA, on the immediate container. Under § 201.66, the regulation implementing section 502(e)(1)(A)(iii) for OTC drugs, inactive ingredients must be listed on the outside container of a retail package or on the immediate container of the product if there is no outside container or wrapper. The association asserts that section 502(e)(1)(B) of the act (21 U.S.C. 352(e)(1)(B)) gives us the ''authority to grant relief from the inactive ingredient listing requirements in appropriate circumstances.'' However, section 502(e)(1)(B) addresses only prescription drug labeling. We do not find a basis for allowing an option to list the inactive ingredients of an OTC drug product in a different location, such as in other labeling accompanying the product.

III. Analysis of Economic Impacts

We have examined the impacts of this final rule under Executive Order 12866, 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 believe 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. This rule provides an additional statement of identity for OTC skin protectant drug products. The revision provides manufacturers of OTC lip protectant drug products the option to label their products as a ''lip protectant'' or ''lip balm'' in addition to ''skin protectant,'' as required by the monograph. The rule also allows manufacturers to omit a warning if the packaging meets the requirements of § 201.66(d)(10). Thus, this rule does not impose any new requirements. Rather, manufacturers may make these changes if they wish to do so. If manufacturers choose to make the changes, they may do so when ordering new labeling in the normal course of business. Therefore, we do not believe that this final rule will 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 $127 million, using the most current (2006) 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.

IV. 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)).

V. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this final rule has 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 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. Section 751(b) through (e) of the act outlines the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.

This final rule provides an additional statement of identity for skin protectants formulated and marketed as lip protectants and allows omission of a warning for certain lip protectant products. Any final rule has a preemptive effect in that it precludes States from issuing requirements related to the labeling of OTC skin protectant 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 US 861 (2000)).

We believe that the preemptive effect of the final rule is 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 on the reduced labeling requirements that this rulemaking addresses, through publication of the request for comments in the **Federal Register** in the preamble to the final rule on June 4, 2003 (68 FR 33362). We received no comments from any States in response to the request.

In addition, on December 10, 2007, FDA's Division of Federal and State Relations provided notice via e-mail transmission to elected officials of State governments and their representatives of national organization. The notice provided the States with further opportunity to comment. It advised the States of the publication of the request for comments and encouraged State and local governments to review the request and to provide any comments to the dockets for this rulemaking (Docket Nos. 1978N–0021 and 1978N–0021P) by a date 30 days after the date of the notice (i.e., by January 10, 2008), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the previously mentioned dockets.

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.

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. References

The following references are on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 under Docket No. 1978N–0021 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. C67.
2. Comment No. C68.
3. Comment No. C69.

List of Subjects in 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 part 347 is amended as follows:

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

■ 1. 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.

■ 2. Section 347.50 is amended by revising paragraphs (a) and (e)(1)(iii) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

* * * * *

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following:

(1) *For any product.* ''Skin protectant'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(2) *For any product formulated as a lip protectant.* ''Skin protectant,'' ''lip protectant,'' or ''lip balm'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(3) *For products containing any ingredient in § 347.10(b), (c), (j), (s), (t), and (u).* ''Poison ivy, oak, sumac drying'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(4) *For products containing any ingredient in § 347.10(b), (c), (f), (j), (o), (s), (t), and (u).* ''Poison ivy, oak, sumac protectant.''

* * * * *

(e) *Products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10) of this chapter.* * * *

(1) * * *

(iii) The ''external use only'' warning in § 347.50(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The warnings in § 347.50(c)(2), (c)(3), and (c)(4) are not required.

* * * * *

Dated: January 28, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1818 Filed 1–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for veterinarian prescription use of tulathromycin injectable solution for the treatment of infectious bovine keratoconjunctivitis and the addition of a pathogen to the indication for use for treatment of swine respiratory disease.

DATES: This rule is effective February 1, 2008.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8342, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–244 for DRAXXIN (tulathromycin)