

Accordingly, no regulatory flexibility analysis is required.

Document Availability

9. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's home page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426. The full text of this document is available on the FERC's Home Page at the eLibrary link. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field and follow other directions on the search page.

10. User assistance is available for eLibrary and other aspects of the FERC's Web site during normal business hours. For assistance, contact FERC Online Support at FercOnlineSupport@ferc.gov, or call toll-free at (866) 208-3676, or for TTY, contact (202) 502-8659.

Effective Date

11. These regulations are effective immediately, pursuant to 5 U.S.C. 533(b), upon the date of publication in the **Federal Register**. The Commission is issuing this as a final rule without a period for public comment, because under 5 U.S.C. 533(b), notice and comment procedures are unnecessary where a rulemaking concerns only agency procedure and practice or where the agency finds notice and comment unnecessary. Inasmuch as the change promulgated in this proceeding is consistent with a court remand and subsequent affirmance of the Commission's order on remand, and because substantial public comments have already been made on the substance of the change, the Commission finds that further notice and comment are unnecessary. The provisions of 5 U.S.C. 801 regarding Congressional review of Final Rules does not apply to this Final Rule, because the rule concerns agency procedure and practice and will not substantially affect the rights of non-agency parties.

Congressional Notification

12. The Commission has determined with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this rule is not a major rule within the meaning of section 251 of the Small

Business Regulatory Enforcement Fairness Act of 1996.¹⁶ The Commission will submit the Final Rule to both Houses of Congress and the General Accounting Office.¹⁷

List of Subjects in 18 CFR Part 342

Reporting and recordkeeping requirements.

By the Commission.

Magalie R. Salas,
Secretary.

■ In consideration of the foregoing, the Commission amends part 342, chapter I, title 18, Code of Federal Regulations, as follows:

SUBCHAPTER P—REGULATIONS UNDER THE INTERSTATE COMMERCE ACT

PART 342—OIL PIPELINE RATE METHODOLOGIES AND PROCEDURES

§ 342.3 [Amended]

■ 1. Part 342, section 342.3(d)(2) is amended by removing the words “, and then subtracting 0.01”.

[FR Doc. 04-20084 Filed 9-2-04; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket Nos. 1998N-0337, 1996N-0420, 1995N-0259, and 1990P-0201]

RIN 0910-AA79

Over-the-Counter Human Drugs; Labeling Requirements; Delay of Implementation Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of implementation date of certain provisions.

SUMMARY: The Food and Drug Administration (FDA) is providing a delay of the implementation date for certain products subject to its final rule that established standardized format and content requirements for the labeling of over-the-counter (OTC) drug products (drug facts rule). That final rule requires all OTC drug products to comply with new format and labeling requirements within prescribed implementation periods. The agency intends in a future issue of the **Federal Register** to propose an amendment to

the drug facts rule to modify the labeling requirements for OTC sunscreen drug products. This document postpones the implementation date of the drug facts rule as it applies to OTC sunscreen drug products pending the outcome of the future rulemaking.

DATES: *Effective:* October 4, 2004. FDA is delaying the May 16, 2005, implementation date for the drug facts rule (21 CFR 201.66) as it applies to OTC sunscreen drug products (21 CFR part 352) until further notice.

Comment Date: Submit written or electronic comments by December 2, 2004.

ADDRESSES: You may submit comments, identified by Docket Nos. 1998N-0337, 1996N-0420, 1995N-0259, and 1990P-0201 and/or RIN number 0910-AA79, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/docket/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov.

Include Docket Nos. 1998N-0337, 1996N-0420, 1995N-0259, and 1990P-0201 and/or RIN number 0910-AA79 in the subject line of your e-mail message.

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket numbers or regulatory information number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the dockets to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, 301-827-2307.

¹⁶ See 5 U.S.C. 804(2)(2000).

¹⁷ See 5 U.S.C. 801(a)(1)(A)(2000).

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and standardized content requirements for the labeling of OTC drug products (drug facts rule). Those requirements are codified in § 201.66.

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of all OTC drug products. In the drug facts rule and in subsequent documents, FDA provided different dates by which OTC drug products had to comply with the new requirements. These dates varied according to the regulatory status of the products (64 FR 13254 at 13273 and 13274).

A. Compliance Dates for the Drug Facts Rule

1. Products in the OTC Drug Review

Products for which a final monograph (FM) became effective on or after April 16, 1999, had to comply “as of: (1) The applicable implementation date for that final monograph, (2) the next major revision to any part of the label or labeling after April 16, 2001, or (3) April 18, 2005, whichever occurs first.” Combination drug products in which one or more active ingredients were the subject of an FM, and one or more ingredients were still under review as of the effective date of the drug facts rule, had to comply as of the implementation date for the last applicable FM for the combination, or as of April 16, 2001, whichever occurred first. Combination products in which none of the active ingredients was the subject of an FM or monographs as of the effective date of the drug facts rule had to comply “as of: (1) The implementation date of the last applicable final monograph for the combination, (2) the next major revision to any part of the label or labeling after April 16, 2001, or (3) April 18, 2005, whichever comes first.”

2. Products Marketed Under NDAs and ANDAs

Products that were the subject of a drug application (NDA or ANDA) that was approved before April 16, 1999, had to comply with the drug facts rule as of April 16, 2001. Products that became the subject of an approved NDA or ANDA on or after April 16, 1999, were required to comply with the drug facts rule at the time of approval (64 FR 13254 at 13274).

3. Additional Provisions

In addition, any OTC drug product not described in sections I.A.1 and I.A.2

of this document had to comply with the drug facts rule “as of: (1) The next major revision to any part of the label or labeling after April 16, 2001, or (2) April 18, 2005, whichever occurs first.”

B. Correction Document

In the **Federal Register** of April 15, 1999 (64 FR 18571), FDA published a correction to the drug facts rule and changed its effective date from April 16, 1999, to May 16, 1999. While FDA did not explicitly discuss the implementation plan and compliance dates for the drug facts rule, the correction had the effect of changing the compliance dates for the drug facts rule as follows: (1) The April 16, 1999, compliance date became May 16, 1999; (2) the April 16, 2001, compliance date became May 16, 2001; and (3) the April 18, 2005, compliance date became May 16, 2005.

C. Partial Extension

In the **Federal Register** of June 20, 2000 (65 FR 38191), FDA published a partial extension of compliance dates for the drug facts rule. FDA extended the May 16, 2001, date to May 16, 2002 (and the corresponding May 16, 2002, date for products with annual sales of less than \$25,000 to May 16, 2003). The May 16, 2005, date was not changed. FDA did not extend the date for products marketed under an NDA or ANDA approved after May 16, 1999. FDA also made one minor change in the implementation chart that appeared in the drug facts rule (64 FR 13254 at 13274). That change involved combination products subject to an OTC drug monograph or monographs in which at least one applicable monograph was finalized before May 16, 1999, and at least one applicable monograph was finalized on or after May 16, 1999. The final rule had stated the compliance date for such products as “Within the period specified in the last applicable monograph to be finalized, or by May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than \$25,000), whichever occurs first.” FDA recognized that some final monographs may be finalized close to the May 16, 2002, date. If that occurred, relabeling might be required at two closely related time intervals by two different final rules. FDA added that it would be aware of that possibility when the last applicable monograph is published and would make allowance there to avoid this dual relabeling within a short time period. Therefore, at the end of the time period for this specific type of combination product in the implementation chart, FDA added the words “unless the last applicable

monograph to be finalized specifies a later date.” The restated implementation chart can be found at 65 FR 38191 at 38193. FDA concluded that this additional language should alleviate any possible ambiguities that might have existed about when relabeling required by two different rules would have to occur. A similar concept applies to FDA’s delay of the drug facts rule for OTC sunscreen drug products discussed in section III of this document.

II. Stay of the FM for OTC Sunscreen Drug Products

In the **Federal Register** of May 21, 1999 (64 FR 27666), FDA published the FM for OTC sunscreen drug products in part 352. In the **Federal Register** of December 31, 2001 (66 FR 67485), FDA stayed that final rule until further notice. FDA issued that partial stay because it intends to propose amendments to part 352 that address both ultraviolet A and ultraviolet B radiation protection. FDA stated that because the agency has not yet published the proposed amendment to part 352, it is not possible for manufacturers of OTC sunscreen drug products to relabel and test their products in accord with an amended FM by the, then current, effective date of December 31, 2002. Accordingly, FDA stayed part 352 until further notice could be provided in a future issue of the **Federal Register**. FDA added that it anticipated the new effective date would not be before January 1, 2005. The future document will contain proposed amendments to the drug facts labeling currently included in part 352 for OTC sunscreen drug products. At this time, FDA has not completed the proposed amendment of the sunscreen FM discussed in the December 31, 2001, stay.

III. FDA’s Delay of the Drug Facts Rule for OTC Sunscreen Drug Products

FDA has determined that a final amendment of the sunscreen FM will not be completed by the May 16, 2005, final implementation date for the OTC drug facts rule. FDA hopes to publish the final amendment of the sunscreen FM shortly after the May 16, 2005, implementation date. Thus, to avoid dual relabeling that might be required at two closely related time intervals by two different final rules, FDA believes the final implementation date for the OTC drug facts rule should also be concurrently delayed as it applies to OTC sunscreen drug products. For these reasons, FDA is delaying the May 16, 2005, implementation date for the drug facts rule as it applies to OTC sunscreen drug products until further notice. The

new implementation date for these products will be coordinated with the lifting of the stay for OTC sunscreen drug products covered by part 352.

The delay in the implementation date for OTC sunscreen drug products will remain in effect until FDA publishes an amended FM and provides a new compliance date or until FDA issues further notice. In either case, the delay enables manufacturers of these products to continue marketing them in their present labeling formats pending completion of the amended FM. The labeling of these products still needs to comply with the Federal Food, Drug, and Cosmetic Act (the act) and other applicable regulatory requirements. Notwithstanding this delay in the implementation date, manufacturers who wish to do so may still relabel the affected products in the drug facts format, particularly when existing labeling is exhausted and relabeling would occur in the normal course of business.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, FDA's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. FDA is delaying the compliance date of § 201.66 for OTC sunscreen drug products because it intends to amend the FM for those products in the near future. That amendment will propose a new compliance date for those products to implement § 201.66 and provide an opportunity to comment on this new date. In addition, given the imminence of the current implementation date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that FDA would be proposing to extend the implementation date for § 201.66, those companies affected would have to be preparing to relabel to comply with the May 16, 2005, implementation date. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this delay should be modified or revoked.

IV. Delay of May 16, 2005, Implementation Date for Other OTC Drug Products

FDA is not delaying the May 16, 2005, implementation date for the drug facts rule for any other OTC drug products in this document. In a restated implementation chart for the drug facts rule published in the **Federal Register** of April 5, 2002 (67 FR 16304 at 16306 to 16307), FDA stated different dates by which OTC single entity or combination drug products had to comply with the drug facts rule when OTC drug monographs were finalized after May 16, 1999. In all cases, the final implementation date was May 16, 2005, unless an FM specifies a different time period. At this time, no FM has specified a different time period. FDA intends that all OTC drug products comply with the May 16, 2005, implementation date for the drug facts rule even if a final OTC drug monograph has not issued for a specific drug product class. The only other exceptions are as follows: (1) OTC sunscreen drug products discussed in this document and (2) OTC "convenience-size" drug products discussed in the April 5, 2002, partial delay of compliance dates for labeling requirements for OTC human drugs.

V. Analysis of Impacts

The economic impact of the drug facts rule was discussed in the final rule (64 FR 13254 at 13276 to 13285). This partial delay of the May 16, 2005, implementation date for OTC sunscreen drug products provides additional time for companies to relabel certain products to comply with an amended FM, to be published in a future issue of the **Federal Register**. This delay will also reduce label obsolescence as companies will have additional time to use up more existing labeling. Thus, delaying the implementation date for these specific products will significantly reduce the economic impact of the final rule on manufacturers of these products.

FDA has examined the impacts of this final rule (partial delay of the compliance date) 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).

Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on 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."

FDA concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. This final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. As discussed in this section, FDA has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule because the final rule is not expected to result in any 1-year expenditure that would meet or exceed \$100 million adjusted for inflation. The current threshold after adjustment for inflation is about \$110 million.

The purpose of this final rule is to provide a partial delay of the May 16, 2005, implementation date by which manufacturers need to relabel their OTC sunscreen drug products. Accordingly, under the Regulatory Flexibility Act, FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Environmental Impact

FDA has 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.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. Authority

This final rule (partial delay of compliance date) is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the act (21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under authority of the Commissioner of Food and Drugs.

Dated: July 30, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-18842 Filed 9-2-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9137]

RIN 1545-BA81

Partnership Transactions Involving Long-Term Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD 9137) that were published in the **Federal Register** on Friday, July 16, 2004 (69 FR 42551) relating to partnership transactions involving contracts accounted for under a long-term contract method of accounting.

DATES: This correction is effective July 16, 2004.

FOR FURTHER INFORMATION CONTACT: Richard Probst at (202) 622-3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under section 460 of the Internal Revenue Code.

Need for Correction

As published, TD 9137 contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 9137), which was the subject of FR Doc. 04-15833, is corrected as follows:

§ 1.1362-3 [Corrected]

■ 1. On page 42559, column 2, § 1.1362-3, Par. 14., second line, the language, “by adding a sentence is at the end of” is corrected to read “by adding a sentence at the end of”.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedures and Administration).

[FR Doc. 04-20166 Filed 9-2-04; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP-1129-I]

RIN 1120-AB29

Over-The-Counter (OTC) Medications: Technical Correction

AGENCY: Bureau of Prisons, Justice.

ACTION: Interim final rule.

SUMMARY: This document makes a minor technical correction to the Bureau of Prisons (Bureau) regulations on Over-The-Counter (OTC) medications. Previously, our rule defined an inmate without funds as one who has had an

average daily trust fund account balance of less than \$6.00 for the past 30 days. The words “average daily” in that definition resulted in incorrect classifications by the Bureau’s business offices. The more accurate definition of an inmate without funds is one who has not had a trust fund account balance of \$6.00 for the past 30 days. We therefore issue this technical correction.

DATES: This rule is effective September 3, 2004. Comments are due by November 2, 2004.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. Our e-mail address is BOPRULES@BOP.GOV.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307-2105.

SUPPLEMENTARY INFORMATION: We amend our regulations on Over-The-Counter (OTC) medications (28 CFR part 549, subpart B). We published a final rule on this subject in the **Federal Register** on August 12, 2003 (68 FR 47847).

Previously, our rule defined an inmate without funds as one who has had an average daily trust fund account balance of less than \$6.00 for the past 30 days. The words “average daily” in that definition resulted in incorrect classifications by the Bureau’s business offices. The more accurate definition of an inmate without funds is one who has not had a trust fund account balance of \$6.00 for the past 30 days. We therefore issue this technical correction.

Administrative Procedure Act

The Administrative Procedure Act (5 U.S.C. 553) allows exceptions to notice-and-comment rulemaking “when the agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”

This rulemaking is exempt from normal notice-and-comment procedures because it makes a minor technical correction in the wording of a definition. This change does not change the substance or application of the definition. This rulemaking makes no change to any rights or responsibilities of the agency or any regulated entities. Because this minor change is of a practical nature, normal notice-and-comment rulemaking is unnecessary. The public may, however, comment on this rule change because it is an interim final rule.