

conversations will be included on an optional basis and meetings with the working press, except for "house organs" (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors will not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees will be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) The calendar will include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar will specify the date and the person and subject matter involved. When more than one FDA representative is in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. Meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in FDA) will not be reported.

(3) The following FDA representatives and their deputies are subject to the requirements of paragraphs (b)(1) and (2) of this section:

- (i) Commissioner of Food and Drugs.
- (ii) Deputy Commissioner.
- (iii) Associate Commissioners.
- (iv) Executive and Special Assistants to the Commissioner.
- (v) [Reserved]
- (vi) Director, National Center for Toxicological Research.
- (vii) Center Directors.
- (viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

(4) A copy of the public calendar will be placed on public display in the following places:

- (i) Dockets Management Branch.
- (ii) Office of the Associate Commissioner for Public Affairs.
- (iii) A central place in each center.
- (iv) A central place in each field office.
- (v) A central place at the National Center for Toxicological Research.

#### **PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE**

10. The authority citation for 21 CFR part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394,

467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

11. Section 14.20 is amended by adding paragraph (e) from January 22, 2001, to April 22, 2001, to read as follows:

#### **§ 14.20 Notice of hearing before an advisory committee.**

\* \* \* \* \*

(e) All advisory committee meetings are to be included on the public calendar described in § 10.100(a).

#### **PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

12. The authority citation for 21 CFR part 16 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

13. Section 16.60 is amended by adding paragraph (a)(3) from January 22, 2001, to April 22, 2001, to read as follows:

#### **§ 16.60 Hearing procedure.**

(a) \* \* \*

(3) If the hearing is a public hearing, it will be announced on the public calendar described in § 10.100(a) whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

\* \* \* \* \*

Dated: February 23, 2001.

**Ann M. Witt,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 01–4962 Filed 2–28–01; 8:45 am]

**BILLING CODE 4160–01–S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

##### **21 CFR Parts 203 and 205**

**[Docket No. 92N–0297]**

**RIN 0905–AC81**

#### **Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is further delaying, until April 1, 2002, the

effective date regarding certain requirements of the final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA is further delaying the effective date for certain requirements in the PDMA final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a "health care entity" in the final rule. In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency previously delayed until October 1, 2001, the effective date of these requirements. The other provisions of the final rule became effective on December 4, 2000. The agency is taking this action to address concerns about the requirements raised by affected parties.

FDA believes that this further delay of the effective date of certain requirements in the PDMA final rule satisfies the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled "Regulatory Review Plan," published in the **Federal Register** on January 24, 2001 (66 FR 7702). That memorandum requested Federal agencies to delay by 60 days the effective date of any regulation that was not effective as of January 20, 2001. The action taken in this document to further delay the effective date of certain requirements of PDMA exceeds 60 days. 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)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. As explained in the **SUPPLEMENTARY INFORMATION** section entitled "Need to Further Delay the Effective Date," the delay will give distributors additional time to exhaust inventories of drugs that do not have acceptable pedigrees to avoid economic harm. Additionally, the delay will allow more time for FDA to make recommendations to Congress, for Congress to evaluate those recommendations and, if necessary,

time for a regulatory or legislative change.

**DATES:** The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until April 1, 2002.

**FOR FURTHER INFORMATION CONTACT:** Lee D. Korb, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Legislative and Regulatory Requirements for Distribution of Prescription Drugs by Unauthorized Distributors*

PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs.

Section 503(e)(1)(A) of the act states that each person who is engaged in the wholesale distribution of a prescription drug who is not the manufacturer or an authorized distributor of record for the drug must, before each wholesale distribution of a drug, provide to the person receiving the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction.<sup>1</sup> Section 503(e)(4)(A) of the act states that, for the purposes of section 503(e), the term "authorized distributors of record" means those distributors with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing these and other provisions of PDMA (64 FR 67720). Section 203.50 requires that, before the completion of any wholesale distribution of a prescription drug by a wholesale distributor that is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller must provide to the

purchaser a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer, and the date of each previous transaction. Section 203.3(b) defines "authorized distributor of record" as a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. "Ongoing relationship" is defined in § 203.3(u) to mean an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Thus, the final rule requires unauthorized distributors (i.e., those distributors who do not have a written authorization agreement) to provide a drug origin statement to purchasers showing the entire prior sales history of the drug back to the first sale by the manufacturer. As discussed in the preamble to the final rule (64 FR 67720 at 67747), manufacturers and authorized distributors of record are not required to provide an identifying statement when selling a drug, although the agency encouraged them to do so voluntarily to permit unauthorized distributors to continue to be able to purchase products from them.<sup>2</sup>

*B. Legislative and Regulatory Requirements Restricting Distribution of Blood Derived Prescription Drug Products by Health Care Entities*

Section 503(c)(3)(A) of the act states that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity. Section 503(c)(3)(B) of the act states several exceptions to section

503(c)(3)(A), none of which are relevant to this discussion. Section 503(c)(3) of the act also states that "[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law."

Section 203.20 of the final rule provides, with certain exceptions, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization. In § 203.3(q) of the final rule, "Health care entity" is defined as meaning any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or wholesale distributor. Under both the act and the final rule, a person could not simultaneously be a health care entity and a retail pharmacy or wholesale distributor. Thus, under the final rule, blood centers functioning as health care entities could not engage in wholesale distribution of prescription drugs, except for blood and blood components intended for transfusion, which are exempt from the PDMA under § 203.1 of the final rule. Blood and blood components include whole blood, red blood cells, platelets, and cryoprecipitated antihemophilic factor, which are prepared by blood banks who collect blood from donors and separate out the components using physical or mechanical means. Blood derivatives are derived from human blood, plasma, or serum through a chemical fractionation manufacturing process. Examples of blood derivative products include albumin, antihemophilic factor, immune globulin, and alpha-1 anti-trypsin. As discussed in the preamble to the final rule in response to comments (64 FR 67720 at 67725 through 67727), blood derivative products are not blood or blood components intended for transfusion and therefore could not be distributed by health care entities, including full service blood centers that function as health care entities, after the final rule goes into effect.

*C. Events Leading to the Delay of the Effective Date*

After publication of the final rule, the agency received letters and petitions and had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry

<sup>1</sup> The statement required under section 503(e)(1)(A) of the act is commonly referred to as a drug "pedigree."

<sup>2</sup> An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50.

associations to discuss their concerns. In addition, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the submissions on wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve. The blood center industry asserts that the regulations, and particularly the definition of "health care entity," will severely inhibit their ability to provide medical care and services to the detriment of client hospitals and the patients they serve, and may disrupt the distribution of blood derivatives to the public. The agency also received a letter from Congress on this issue.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency published a document in the **Federal Register** of May 3, 2000 (65 FR 25639), delaying the effective date for those provisions until October 1, 2001. In addition, the May 2000 document delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001. The May 2000 document also reopened the administrative record and gave interested persons until July 3, 2000, to submit written comments. As stated in the May 2000 document, the purpose of delaying the effective date for these provisions was to give the agency time to obtain more information about the possible consequences of implementing them and to further evaluate the issues involved.

#### *D. House Committee on Appropriations Reaction to Agency Delay and Committee's Report Request*

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106-619) that it supported the "recent FDA action to delay the effective date for implementing certain

requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments." In addition, the Committee stated that it "believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry." The Committee directed the agency to provide a report to the Committee by January 15, 2001, summarizing the comments and issues raised and agency plans to address the concerns.

#### *E. Public Hearing*

After issuing the delay of the effective date for the relevant requirements of the final rule, the agency decided that it would be in the public interest to hold a public hearing to elicit comment on the requirements from interested persons. In the **Federal Register** of September 19, 2000 (65 FR 56480), the agency announced that a public hearing would be held on October 27, 2000, to discuss the requirements at issue (i.e., the requirements for unauthorized distributors and the provisions relating to distribution of blood derivatives by health care entities). The document set forth the purpose of the hearing and the procedure by which individuals could make a presentation at the hearing. In addition, the document set forth questions the agency wanted hearing participants and comments to address. The hearing was held on October 27, 2000, and comments were accepted until November 20, 2000.

#### **II. Need to Further Delay the Effective Date**

As discussed in section I of this document, the House Committee on Appropriations has directed the agency to provide a report to the Committee by January 15, 2001, summarizing the comments and issues raised and agency plans to address the concerns. The agency is currently considering the comments and testimony received and preparing its report to Congress. If the agency determines that some type of action is appropriate, this action could take the form of a change or modification to the final rule initiated by the agency or a legislative change initiated by Congress. Obviously, it would take a significant amount of time beyond January 15, 2001, to initiate and carry out either change. The agency believes that a legislative change to the act could take well into the 2001 calendar year.

In its hearing testimony and in a letter submitted on November 3, 2000, the Pharmaceutical Distributors

Association<sup>3</sup> noted that if the final rule were to apply to drugs already in distribution as of the effective date of the final rule, a significant number of these drugs would have to be taken out of distribution because of the absence of a proper pedigree. The association specifically stated that if the final rule as published were to go into effect October 1, 2001, distributors would need to stop buying drugs that do not have the required pedigree under the final rule and would have to begin to exhaust existing inventories of drugs that do not have acceptable pedigrees by the beginning of the year 2001 to avoid economic harm. The association specifically sought a decision by the agency that the final rule not apply to prescription drugs already in distribution as of the effective date so those drugs could be distributed.

FDA acknowledges the concerns of the Pharmaceutical Distributors Association and has decided that, in light of the uncertainty regarding how to resolve the issues involved and the possible adverse consequences that could result from implementation of the relevant provisions of the final rule, it is reasonable and appropriate to delay the effective date of §§ 203.3(u) and 203.50 for another 6 months until April 1, 2002. Additionally, the agency has decided to delay the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until April 1, 2002. This delay will allow time for the agency to make its recommendations to Congress, for Congress to evaluate those recommendations, and, depending on the decisions of the agency and Congress, for a regulatory or legislative change to address the issues raised. Although a further delay of the effective date of the relevant provisions of the final rule is not the exact relief requested by the Pharmaceutical Distributors Association, the agency believes that it accomplishes the same purpose in that it will permit unauthorized distributors to operate for an additional 6 months without concern that the drugs in their inventory may become illegal to distribute and therefore valueless. All other provisions of the PDMA final rule became effective on December 4, 2000. This action should not be construed to indicate that FDA necessarily agrees with or has made decisions about the substantive arguments made in the petitions and other submissions related to implementation of §§ 203.3(u) and

<sup>3</sup>The Pharmaceutical Distributors Association is a trade association representing unauthorized wholesale prescription drug distributors.

203.50, or § 203.3(q), as it applies to wholesale distribution of blood derivatives by health care entities.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this further delay of the effective date is in the public interest.

Dated: February 22, 2001.

**Ann M. Witt,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 01-4964 Filed 2-28-01; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 8934]

RIN 1545-AX60

#### Reopenings of Treasury Securities and Other Debt Instruments; Original Issue Discount; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to final regulations.

**SUMMARY:** This document contains corrections to final regulations that were published in the **Federal Register** on Friday, January 12, 2001 (66 FR 2811), relating to reopenings of Treasury securities, other debt instruments, and original issue discount.

**DATES:** This correction is effective March 13, 2001.

**FOR FURTHER INFORMATION CONTACT:** William E. Blanchard, (202) 622-3950 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

#### Background

The final regulations (TD 8934) that are the subject of these corrections are under section 1275 of the Internal Revenue Code.

#### Need for Correction

As published the final regulations (TD 8934) contain errors that may prove to be misleading and are in need of clarification.

#### Correction of Publication

Accordingly, the publication of the final regulations (TD 8934), which were the subject of FR Doc. 01-622, is corrected as follows:

On page 2813, column 2, in the preamble under the heading "(2) Yield Test", second line from the bottom of the column the language "percent test in the proposed regulations" is corrected

to read "percent test in the proposed regulations".

**Cynthia E. Grigsby,**

*Chief, Regulations Unit, Office of Special Counsel (Modernization & Strategic Planning).*

[FR Doc. 01-4922 Filed 2-28-01; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Parts 19 and 21

[T.D. ATF-442; Ref: Notice No. 832]

RIN 1512-AB60

#### Formulas for Denatured Alcohol and Rum (2000R-295P)

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

**ACTION:** Final Rule (Treasury decision).

**SUMMARY:** This final rule amends the regulations in 27 CFR Parts 19 and 21 by updating the information relating to the formulation of completely denatured alcohol (CDA), specially denatured alcohol (SDA), and specially denatured rum (SDR); the denaturants authorized for use in the manufacturing of these formulations; and the specifications for these denaturants. The updates include removing the proprietary brand name "BITREX" listed with the denaturant denatonium benzoate, incorporating an ATF ruling that approves the use of two substitute denaturants, and making other amendments to provide clarity.

**DATES:** This rule is effective on March 1, 2001.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226, (202-927-9347) or e-mail at [alctob@atfhq.atf.treas.gov](mailto:alctob@atfhq.atf.treas.gov).

**SUPPLEMENTARY INFORMATION:**

#### Background

27 CFR Part 21 contains listings of information relating to the formulation of CDA, SDA, and SDR, to the specifications for denaturants and to the denaturants authorized for use in the formulation of CDA, SDA, and SDR. ATF is authorized under § 5242 of the Internal Revenue Code of 1986 to prescribe the character and quantity of approved denaturing materials. Pursuant to § 21.91, ATF may authorize substitutions or variations from the specified list of denaturants upon

application filed with ATF by the denaturer. This final rule amends Part 21 by incorporating additional denaturants that have been approved pursuant to such applications. Additionally, this final rule incorporates several technical corrections.

#### Substitute Denaturants

ATF Ruling 94-4 approved the use of heptane as a substitute denaturant for toluene in SDA Formula No. 2-B (SDA 2-B) and alpha terpineol as a substitute denaturant in SDA Formula No. 38-B (SDA 38-B).

Heptane is currently approved as a substitute denaturant for rubber hydrocarbon solvent in SDA 28-A. This ruling allows for the use of heptane as a substitute, on an equal (1:1) basis, for any one of the denaturants (toluene, benzene or rubber hydrocarbon solvent) in SDA 2-B.

Alpha terpineol, having similar specifications to those of pine oil, N.F., an approved denaturant for SDA 38-B, is now approved for use as a substitute denaturant in SDA 38-B.

#### Removal of a Proprietary Name

This final rule removes the proprietary brand name "BITREX" each place it appears in parts 19 and 21. The use of the proprietary brand name "BITREX" in conjunction with the approved denaturant denatonium benzoate, N.F. may be mistakenly considered a product endorsement by ATF over all over proprietary names.

#### Other Changes

27 CFR 21.6 and 21.141 are amended to correctly cite referenced information.

#### Notice of Proposed Rulemaking

On July 31, 1996, ATF published a notice of proposed rulemaking (Notice No. 832, 61 FR 39929-39931) to solicit public comment on regulations to update the information provided in parts 19 and 21 relating to the formulation of CDA, SDA, and SDR; the denaturants authorized for use in the manufacturing of these formulations; and the specifications for these denaturants. The comment period closed on September 30, 1996.

#### Comments on the NPRM

ATF did not receive any comments in response to Notice 832, therefore, most of the amendments proposed in Notice No. 832 have been adopted in this final rule.

#### Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, and its implementing