Dated: April 21, 1995.
By the Commission.
Margaret H. McFarland,
Deputy Secretary.
[FR Doc. 95–10487 Filed 4–27–95; 8:45 am]
BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. 88N–0320]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls; Partial Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing a continuation of the partial extension of the compliance date for a provision of the final rule, which was published in the **Federal Register** of August 3, 1993 (58 FR 41348). The document revised the current good manufacturing practice (CGMP) regulations for certain labeling control provisions. In the **Federal Register** of August 2, 1994 (59 FR 39255), FDA partially extended the compliance date for a provision of the regulation to August 3, 1995, and requested comments on the scope of this provision. The agency is further extending the compliance date to August 2, 1996. FDA is taking this action in order to adequately assess comments received on the scope of a particular provision of that rule.

DATES: The final rule published at 58 FR 41348, August 3, 1993, is effective August 3, 1994. The date for compliance with § 211.122(g) for items of labeling (other than immediate container labels) is extended to August 2, 1996. The date of compliance for all other provisions of the final rule remains August 3, 1994.

FOR FURTHER INFORMATION CONTACT:
Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046, or
Paul J. Motise, Center for Drug Evaluation and Research (HFD–323), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1089.

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of August 3, 1993 (58 FR 41348), FDA published a final rule that amended the CGMP regulations to require that certain special control procedures be instituted if cut labeling is used. One of these procedures requires the use of "appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations" (§ 211.122(g)(2)).

On May 4, 1994, FDA received a citizen petition from five trade associations requesting that the agency take a number of actions including, but not limited to, extending the August 3, 1994, effective date of this rule as it applies to labeling (other than the immediate container labels) as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(m)). The petition stated that additional time was needed because of the unavailability of bar code or machine readers as well as other equipment necessary to orient the labeling codes properly, and requested that FDA reopen its administrative record to reassess the scope of a certain provision of the regulation, as discussed below in this document.

On May 6, 1994, the agency received an additional petition from a trade association that requested, among other things, a 1-year stay of the effective date; the petitioner stated that additional time was needed to locate, install, and validate scanning equipment and other necessary equipment to orient items properly for bar code scanning.

Appropriate electronic or electromechanical equipment primarily consists of systems that scan identity codes printed on labeling. If an incorrect code is detected, the defective labeling is ejected from the labeling line. FDA contacted vendors of this equipment and determined that while there was not a general shortage of system hardware, there was a possible shortage of contract engineering firms employed by some drug manufacturers to evaluate, select, purchase, install, qualify, and validate labeling verification systems.

In response to this situation, FDA extended the compliance date of § 211.122(g) as it applied to items of labeling (other than the immediate container label) to assess further the availability of equipment necessary for compliance with the final rule and to evaluate adequately other issues raised by petitioners.

The first petition also requested that the agency reopen the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling (other than that of the immediate container label) as defined in section 201(m) of the act. Both citizen petitions contended that § 211.122(g) expanded the proposed scope of the provision from immediate container labels to all drug product labeling.

In response to the issues raised, FDA agreed to receive comments on this issue and to evaluate those comments in light of the existing language of § 211.122(g). The comment period ended on October 4, 1994, and since that time FDA has had a number of meetings with representatives of the labeling industry and others to determine control options available through current technology and to evaluate this information in light of comments received during the extended comment period.

In order to adequately assess this information, determine whether any possible revision of the regulation should result, and provide industry adequate time to fully comply with a final regulation, FDA is extending the compliance date of § 211.122(g) as its applies to items of labeling other than the immediate container label to August 2, 1996. Should FDA determine, after completing its assessment of the comments, that § 211.122(g) should be retained in its current state or revised, FDA will provide notice of that decision in a future issue of the **Federal Register**. The compliance date for the remainder of § 211.122, including § 211.122(g) as it applies to immediate container labels, was August 3, 1994. The agency emphasizes, however, that § 211.125 makes a waiver of labeling reconciliation conditional on a 100-percent examination for correct labeling performed in accordance with § 211.122(g)(2).

Dated: April 24, 1995.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 95–10461 Filed 4–27–95; 8:45 am]
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21 CFR Part 310

[Docket No. 77N–334S]

RIN 0905–AA06

Topical Drug Products for Over-the-Counter Human Use; Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Final Rule; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of February 15, 1995 (60 FR 8916). The document established that any over-the-counter (OTC) drug product for the prevention of swimmer's ear or for the drying of water-clogged ears is not generally recognized as safe and effective and is misbranded. The document was published with a typographical error in the codified section. This document corrects that error.

EFFECTIVE DATE: August 15, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

In FR Doc. 95–3803, appearing on page 8916, in the **Federal Register** of Wednesday, February 15, 1995, the following correction is made:

§ 310.545 [Corrected]

1. On page 8920, in the third column, under § 310.545, in paragraph (d)(1), in lines 2 and 3, "(a)(1) through (a)(2)(i), (a)(3) through (a)(4)" is corrected to read "(a)(1) through (a)(4)".

Dated: April 24, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–10542 Filed 4–27–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8594]

RIN 1545–AS97

Losses on Small Business Stock

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations amending regulations under section 1244 relating to losses on small business stock. The final regulations remove the requirement that a taxpayer claiming a section 1244 ordinary loss file an information statement with the taxpayer's income tax return.

DATES: These regulations are effective April 27, 1995.

For dates of applicability of these regulations, see "Effective Date" under **SUPPLEMENTARY INFORMATION** portion of preamble.

FOR FURTHER INFORMATION CONTACT: Kirsten L. Simpson, (202) 622–7790 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)) under control number 1545–1447. The estimated annual burden per recordkeeper varies from .10 hours to .30 hours, depending on individual circumstances, with an estimated average of .20 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Background

On November 15, 1994, a notice of proposed rulemaking (CO–46–94), amending regulations under section 1244 of the Internal Revenue Code relating to losses on small business stock, was published in the **Federal Register** (59 FR 58800). No public hearing was requested or held.

One written comment responding to the notice was received. The comment was favorable. The regulations proposed by CO–46–94 are adopted without revision by this Treasury decision.

Explanation of Provision

Section 1.1244(e)–1(b) of the Income Tax Regulations is revised to eliminate the requirement that a taxpayer file an information statement with the taxpayer's income tax return. However, because a taxpayer who claims an ordinary loss under section 1244 still bears the burden of establishing that the deduction is proper, § 1.1244(e)–1(b) is revised to state that a person who claims an ordinary loss with respect to stock under section 1244 must have records sufficient to establish that the taxpayer is entitled to the loss and satisfies the requirements of section 1244.

Effective Date

These regulations are effective for open taxable years beginning after December 31, 1953, the effective date of Treasury Decision 6495, which prescribed regulations under section 1244.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Kirsten L. Simpson, Office of Assistant Chief Counsel (Corporate), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * * Section 1.1244(e)–1 also issued under 26 U.S.C. 1244(e). * * *

Par. 2. Section 1.1244(e)–1 is amended as follows:

1. The section heading is revised.

2. In paragraph (a)(1), the reference in the second sentence to "paragraph (c)(2) of § 1.1244(c)–2" is removed and "§ 1.1244(c)–2(b)(2)" is added in its place.

3. Paragraph (b) is revised.

The revisions read as follows:

§ 1.1244(e)–1 Records to be kept.

* * * * *

(b) *By the taxpayer.* A person who claims an ordinary loss with respect to