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List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Add § 201.24 to subpart A to read as follows:

§ 201.24 Labeling for systemic antibacterial drug products.

The labeling of all systemic drug products intended for human use indicated to treat a bacterial infection, except a mycobacterial infection, must bear the following statements:

(a) At the beginning of the label, under the product name, the labeling must state:

To reduce the development of drug-resistant bacteria and maintain the effectiveness of (*insert name of antibacterial drug product*) and other antibacterial drugs, (*insert name of antibacterial drug product*) should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

(b) In the ''Indications and Usage'' section, the labeling must state:

To reduce the development of drug-resistant bacteria and maintain the effectiveness of (*insert name of antibacterial drug product*) and other antibacterial drugs, (*insert name of antibacterial drug product*) should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

(c) In the ''Precautions'' section, under the ''General'' subsection, the labeling must state:

Prescribing (*insert name of antibacterial drug product*) in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

(d) In the ''Precautions'' section, under the ''Information for Patients'' subsection, the labeling must state:

Patients should be counseled that antibacterial drugs including (*insert name of antibacterial drug product*) should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When (*insert name of antibacterial drug product*) is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by (*insert name of antibacterial drug product*) or other antibacterial drugs in the future.

Dated: October 4, 2002.

Mark B. McClellan,

Commissioner of Food and Drugs.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9022]

RIN 1545–BB40

Information Reporting Relating to Taxable Stock Transactions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to temporary regulations.

SUMMARY: This document contains corrections to temporary regulations that were published in the **Federal Register** on November 18, 2002 (67 FR 69468). This document contains temporary regulations under section 6043(c) requiring information reporting by a corporation if control of the corporation is acquired or if the corporation has a recapitalization or other substantial change in capital structure.

DATES: This correction is effective November 18, 2002.

FOR FURTHER INFORMATION CONTACT: Nancy Rose at (202) 622–4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this correction are under section 6043(c) of the Internal Revenue Code.

Need for Correction

As published, the temporary regulations (TD 9022) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the temporary regulations (TD 9022), which is the subject of FR Doc. 02–29199, is corrected as follows:

1. On page 69469, column 2, in the preamble, under the paragraph heading ''Background and Explanation of Provisions'', line 5, the language ''regulations published in proposed rules'' is corrected to read ''regulations published in the proposed rules''.

§ 1.6043–4T [Corrected]

2. On page 69470, column 1, § 1.6043–4T, paragraph (a)(5), the last line in column one, the language ''shareholders who receive cash, stock or'' is corrected to read ''shareholders who receive cash, stock, or''.

3. On page 69472, column 1, § 1.6043–4T, paragraph (h), of *Example 2*, line 1, the language ''Example 2. C, a domestic corporation, and'' is corrected to read ''Example 2. C, a domestic corporation and''.

§ 1.6045–3T [Corrected]

4. On page 69473, column 1, § 1.6045–3T, paragraph (d), line 2, the language ''receives stock, cash or other property'' is corrected to read ''receives stock, cash, or other property''.

Cynthia E. Grigsby,

Chief, Regulations Unit, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 03–2802 Filed 2–5–03; 8:45 am]

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