

the application for official business, and to maintain in one place a complete copy of the application.

(i) *Format of submission.* An applicant may submit portions of the archival copy of the abbreviated application in any form that the applicant and FDA agree is acceptable, except as provided in paragraph (d)(1)(ii) of this section.

(ii) *Labeling.* The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (d)(1)(iii) of this section. This requirement applies to the content of labeling for the proposed drug product only and is in addition to the requirements of paragraph (a)(8)(ii) of this section that copies of the formatted label and all proposed labeling be submitted. Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(iii) *Electronic format submissions.* Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

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## PART 601—LICENSING

■ 5. The authority citation for 21 CFR part 601 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 6. Add 601.14 to subpart C to read as follows:

### § 601.14 Regulatory submissions in electronic format.

(a) *General.* Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files.)

(b) *Labeling.* The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in

electronic format as described in paragraph (a) of this section. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f) that require applicants to submit specimens of the labels, enclosures, and containers, or to submit other final printed labeling. Submissions under this paragraph must be made in accordance with part 11 of this chapter except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

Dated: July 31, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9097]

RIN 1545–AX22

#### Arbitrage Restrictions Applicable to Tax-Exempt Bonds Issued by State and Local Governments

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

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations on the arbitrage restrictions applicable to tax-exempt bonds issued by state and local governments. The regulations affect issuers of tax-exempt bonds and provide a safe harbor for qualified administrative costs for broker's commissions and similar fees incurred in connection with the acquisition of guaranteed investment contracts or investments purchased for a yield restricted defeasance escrow.

**DATES:** *Effective Date:* These regulations are effective February 9, 2004.

*Applicability Date:* For dates of applicability, see § 1.148–11(i) of these regulations.

**FOR FURTHER INFORMATION CONTACT:** Rose M. Weber, (202) 622–3980 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

This document amends 26 CFR part 1 under section 148 of the Internal Revenue Code by providing rules for determining when certain brokers' commissions or similar fees are qualified administrative costs (the final regulations). On August 27, 1999, the

IRS published in the **Federal Register** a notice of proposed rulemaking (REG–105565–99)(64 FR 46876) (the proposed regulations). The proposed regulations modify § 1.148–5(e)(2) to provide a safe harbor for determining whether brokers' commissions and similar fees incurred in connection with the acquisition of guaranteed investment contracts or investments purchased for a yield restricted defeasance escrow are treated as qualified administrative costs. Comments on the proposed regulations were received and a hearing was held on December 14, 1999. After consideration of all the comments, the proposed regulations are adopted as revised by this Treasury decision. The revisions are discussed below.

#### Explanation of Provisions

##### I. Existing Regulations

##### A. Investment Yield and Administrative Costs

Section 148 limits the yield on investments purchased with proceeds of tax-exempt bonds. In general, under § 1.148–5(b)(1) of the existing regulations, the yield on an investment is computed by comparing receipts from the investment to payments for the investment. Section 1.148–5(e)(1) provides that the yield on an investment generally is not adjusted to take into account any costs or expenses paid, directly or indirectly, to purchase, carry, sell, or retire the investment (administrative costs). However, § 1.148–5(e)(2)(i) provides that the yield on nonpurpose investments (as defined in § 1.148–1(b)) is adjusted to take into account qualified administrative costs. Qualified administrative costs are reasonable, direct administrative costs, other than carrying costs, such as separately stated brokerage or selling commissions, but not legal and accounting fees, recordkeeping, custody, and similar costs. In general, under § 1.148–5(e)(2)(i), administrative costs are not reasonable unless they are comparable to administrative costs that would be charged for the same investment or a reasonably comparable investment if acquired with a source of funds other than gross proceeds of tax-exempt bonds (the comparability standard).

##### B. Special Rule for Guaranteed Investment Contracts

Section 1.148–5(e)(2)(iii) of the existing regulations provides that, for a guaranteed investment contract, a broker's commission or similar fee paid on behalf of either an issuer or the guaranteed investment contract provider generally is a qualified administrative