

ordinarily compiles and organizes the information while performing the GST, we anticipate that the additional time

needed to submit an exemption request will be minimal.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.11(g)(2)	10	1	10	40	400

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The direct final rule and companion proposed rule of April 20, 1998 (63 FR 19399 and 19431, respectively) provided a 60-day public comment period on the information collection provisions reflected in this final rule. Although some comments objected to the license supplement mechanism of gaining approval for an exemption as being too burdensome, we received no comments on the actual burden estimates for submitting such supplements.

VII. 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, the agency has concluded that the rule does not contain policies that have federalism implications as defined in that the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Section 610.11 is amended by adding paragraph (g)(2) to read as follows:

§ 610.11 General safety.

* * * * *

(g) * * *

(2) For products other than those identified in paragraph (g)(1) of this section, a manufacturer may request from the Director, Center for Biologics Evaluation and Research, an exemption from the general safety test. The manufacturer must submit information as part of a biologics license application submission or supplement to an approved biologics license application establishing that because of the mode of administration, the method of preparation, or the special nature of the product a test of general safety is unnecessary to assure the safety, purity, and potency of the product or cannot be performed. The request must include alternate procedures, if any, to be performed. The Director, Center for Biologics Evaluation and Research, upon finding that the manufacturer's request justifies an exemption, may exempt the product from the general safety test subject to any condition necessary to assure the safety, purity, and potency of the product.

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-4973 Filed 3-3-03; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 92

[Docket No. FR-4111-C-04]

RIN 2501-AC30

HOME Investment Partnerships Program; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule; correction.

SUMMARY: On October 1, 2002, HUD published a final rule making several streamlining and clarifying amendments to the regulations for the HOME Investment Partnerships Program. The

final rule inadvertently removed the 36-month timeframe for purchasing a home under lease-purchase programs assisted with HOME funds. This document makes the necessary correction to the final rule.

DATES: *Effective Date:* October 1, 2002.

FOR FURTHER INFORMATION CONTACT: Virginia Sardone, Director, Program Policy Division, Office of Affordable Housing Programs, Room 7164, 451 Seventh Street, SW., Washington, DC 20410. Telephone: (202) 708-2470. (This is not a toll-free number.) A telecommunications device for hearing- and speech-impaired persons (TTY) is available at 1-800-877-8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION: On October 1, 2002 (67 FR 61752), HUD published a final rule making several streamlining and clarifying amendments to the regulations for the HOME Investment Partnerships Program. Among other changes, the final rule amended § 92.254(a)(7), which establishes the income eligibility requirements for lease-purchase agreements, to reflect a statutory change made by section 599B of the Quality Housing and Work Responsibility Act of 1998 (Public Law 105-276, approved October 21, 1998) (QHWRA). Section 599B of QHWRA eliminated the requirement that HOME-assisted homebuyers qualify as income eligible at the time of occupancy or when the HOME funds are invested, whichever is later. In the case of a lease-purchase agreement, section 599B requires the homebuyer to qualify as low-income at the time the agreement is signed.

In amending § 92.254(a)(7) to implement section 599B of QHWRA, the October 1, 2002 final rule inadvertently removed the 36-month timeframe for purchasing a home under lease-purchase programs assisted with HOME funds. This provision requires that the home must be purchased by the homebuyer within 36 months of signing the lease-purchase agreement. This document makes the necessary correction to the October 1, 2002 final rule.

Accordingly, rule FR Doc. 02-24820 published on October 1, 2002 (67 FR 61752) is corrected as follows:

1. On page 61756, in the third column, § 92.254(a)(7) is corrected to read as follows:

§ 92.254 Qualification as affordable housing: Homeownership.

(a) * * *

(7) *Lease-purchase.* HOME funds may be used to assist homebuyers through lease-purchase programs for existing housing and for housing to be constructed. The housing must be purchased by a homebuyer within 36 months of signing the lease-purchase agreement. The homebuyer must qualify as a low-income family at the time the lease-purchase agreement is signed. If HOME funds are used to acquire housing that will be resold to a homebuyer through a lease-purchase program, the HOME affordability requirements for rental housing in § 92.252 shall apply if the housing is not transferred to a homebuyer within forty-two months after project completion.

* * * * *

Dated: February 20, 2003.

Roy A. Bernardi,

Assistant Secretary for Community Planning and Development.

[FR Doc. 03-4941 Filed 3-3-03; 8:45 am]

BILLING CODE 4210-29-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 20, 25, 31, 53, 54, 56, 301, and 602

[TD 9046]

RIN 1545-AX81; 1545-BB49; 1545-BB50; 1545-BB48; 1545-BB53; 1545-BB51; 1545-BB52; 1545-AW26; 1545-AX79

Tax Shelter Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: These regulations finalize the rules relating to the filing by certain taxpayers of a disclosure statement with their Federal tax returns under section 6011(a), the rules relating to the registration of confidential corporate tax shelters under section 6111(d), and the rules relating to the list maintenance requirements under section 6112. These regulations affect taxpayers participating in reportable transactions, persons responsible for registering confidential corporate tax shelters, and

organizers and sellers of potentially abusive tax shelters.

DATES: *Effective Date:* These regulations are effective February 28, 2003.

Applicability Date: For dates of applicability, see § 1.6011-4(h), § 20.6011-4(b), § 25.6011-4(b), § 31.6011-4(b), § 53.6011-4(b), § 54.6011-4(b), § 56.6011-4(b), § 301.6111-2(h), and § 301.6112-1(j).

FOR FURTHER INFORMATION CONTACT: Tara P. Volungis or Charlotte Chyr, 202-622-3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control numbers 1545-1685, 1545-1687, and 1545-1686. Responses to these collections of information are mandatory. Form 8886, "Reportable Transaction Disclosure Statement", reflects the collection of information relating to the disclosure of reportable transactions for the regulations under § 1.6011-4, and was approved by OMB under control number 1545-1800. Form 8264, "Application for Registration of a Tax Shelter", reflects the collection of information relating to the registration of tax shelters for the regulations under § 301.6111-2 and § 301.6111-1T, and was approved by OMB under control number 1545-0865.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number assigned by the Office of Management and Budget.

The estimated annual burden per respondent/recordkeeper for the collection of information in § 1.6011-4 will be reflected on Form 8886. The estimated annual burden for the collection of information in Form 8886 is 3,770 hours and the estimated number of respondents/recordkeepers is 500. The estimated annual burden per respondent/recordkeeper for the collection of information in § 301.6111-2 is reflected on Form 8264. The estimated annual burden for the collection of information in Form 8264 is 14,382 hours and the estimated number of respondents/recordkeepers is 350. The estimated annual burden per recordkeeper for the collection of information in § 301.6112-1 is 100 hours and the estimated number of recordkeepers is 500.

Comments concerning the accuracy of these burden estimates and suggestions for reducing these burdens should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:T:T:SP, 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.

Books and records relating to these collections of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document amends 26 CFR part 1 to provide rules relating to the disclosure of reportable transactions by certain taxpayers on their Federal tax returns under section 6011, and also amends 26 CFR parts 20, 25, 31, 53, 54, and 56 to provide rules for purposes of estate, gift, employment, and pension and exempt organizations excise taxes requiring the disclosure of listed transactions by certain taxpayers on their Federal tax returns under section 6011. This document amends 26 CFR part 301 to provide rules regarding the registration of confidential corporate tax shelters under section 6111(d) and rules relating to the list maintenance requirements under section 6112.

On February 28, 2000, the IRS issued temporary and proposed regulations regarding sections 6011, 6111, and 6112 (TD 8877, REG-103735-00; TD 8876, REG-110311-98; TD 8875, REG-103736-00) (the February 2000 regulations). The February 2000 regulations were published in the **Federal Register** (65 FR 11205, 65 FR 11269; 65 FR 11215, 65 FR 11272; 65 FR 11211, 65 FR 11271) on March 2, 2000. On August 11, 2000, the IRS issued temporary and proposed regulations modifying the rules under sections 6011, 6111, and 6112 (TD 8896, REG-103735-00, REG-110311-98, REG-103736-00) (the August 2000 regulations). The August 2000 regulations were published in the **Federal Register** (65 FR 49909, 65 FR 49955) on August 16, 2000. On August 2, 2001, the IRS issued temporary and proposed regulations modifying the rules under sections 6011 and 6111 (TD 8961, REG-103735-00, REG-110311-98) (the August 2001 regulations). The August 2001 regulations were published in the **Federal Register** (66 FR 41133, 66 FR 41169) on August 7, 2001. On June 14, 2002, the IRS issued temporary and