

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 BURDEN ¹

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.

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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.