

manufacture from the formulation submitted for approval, but are similar enough to be relevant to the agency's determination of bioequivalence.

■ 6. Amend § 320.21 by revising the section heading and paragraph (b)(1) to read as follows:

§ 320.21 Requirements for submission of bioavailability and bioequivalence data.

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(b) * * *

(1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in § 314.3(b) of this chapter). A complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval. For all other bioequivalence studies conducted on the same drug product formulation, the applicant must submit either a complete or summary report. If a summary report of a bioequivalence study is submitted and FDA determines that there may be bioequivalence issues or concerns with the product, FDA may require that the applicant submit a complete report of the bioequivalence study to FDA; or

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Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Parts 3 and 5

Protecting the Privacy of Workers: Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction, Effectiveness of Information Collection Requirements

AGENCY: Department of Labor, Employment Standards Administration, Wage and Hour Division.

ACTION: OMB approval of information collection requirements.

SUMMARY: The Office of Management and Budget (OMB) has approved under the Paperwork Reduction Act (PRA) information collection requirements contained in recently revised final regulations published by the Department of Labor in the **Federal Register** on December 19, 2008. The PRA requires this notice to set forth the

effectiveness of information collection requirements contained in a final rule.

DATES: The amendments to §§ 3.3(b) and 5.5(a)(3)(ii)(A) and (B)(1) published in the **Federal Register** on December 19, 2008 (73 FR 77504) have been approved by OMB and are effective January 18, 2009.

ADDRESSES: Written comments regarding the burden-hour estimates or other aspects of the information collection requirements contained in 29 CFR parts 3 and 5 may be submitted to: Administrator, Wage and Hour Division, Room S3502, 200 Constitution Avenue, NW., Washington DC 20210.

FOR FURTHER INFORMATION CONTACT: Richard M. Brennan, Director, Division of Interpretations and Regulatory Analysis, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S-3506, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-0051.

Questions of interpretation and/or enforcement of regulations referenced in this notice may be directed to the nearest Wage and Hour Division (WHD) District Office. Locate the nearest office by calling the WHD toll-free help line at (866) 4US-WAGE ((866) 487-9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto the WHD's Web site for a nationwide listing of WHD District and Area Offices at: <http://www.dol.gov/esa/whd/america2.htm>.

This notice is available through the printed **Federal Register** and electronically via the <http://www.gpoaccess.gov/fr/index.html> Web site.

Copies of this notice may be obtained in alternative formats (Large Print, Braille, Audio Tape or Disc), upon request, by calling (202) 693-0023. TTY/TDD callers may dial toll-free (877) 889-5627 to obtain information or request materials in alternative formats.

SUPPLEMENTARY INFORMATION: On December 30, 2008, the Office of Management and Budget (OMB) approved under the PRA the Department of Labor's information collection request for requirements in 29 CFR 5.5(a)(3)(ii)(A), and 5.5(a)(3)(ii)(B)(1), as published in the **Federal Register** on December 19, 2008. See 73 FR 77504. The current expiration date for OMB authorization for this information collection is December 31, 2011. The regulations implement Davis-Bacon and Related Acts and the Copeland Anti-Kickback Act requirements, and the regulatory changes reduce respondent burden and improve privacy protections for laborers and mechanics employed on federally

financed or assisted construction contracts by lessening the transmission of personal information regarding individuals who work on contracts subject to Davis-Bacon Act labor standards. The preamble to the new regulations stated a general effective date of January 18, 2009; however, the OMB had not yet provided a PRA-required approval for the revised information collection requirements contained in 29 CFR 3.3, 5.5(a)(3)(ii)(A), and 5.5(a)(3)(ii)(B)(1) at the time of their publication. 44 U.S.C. 3507(a)(2). An agency may not conduct an information collection unless it has a currently valid OMB approval; therefore, in accordance with the PRA, the effective date of the information collection requirements in the revised regulations was delayed until the OMB approved them under the PRA. 44 U.S.C. 3506(c)(1)(B)(iii)(V). On December 30, 2008, the OMB approved the Department's information collection request under Control Number 1215-0149; thus, giving effect to the requirements, as announced and published in the **Federal Register** on December 18, 2008, under the PRA. The current expiration date for OMB authorization for this information collection is December 31, 2011.

Dated: January 9, 2009.

Victoria A. Lipnic,

Assistant Secretary, Employment Standards Administration.

Alexander J. Passantino,

Acting Administrator, Wage and Hour Division.

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DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 825

The Family and Medical Leave Act of 1993, Effectiveness of Information Collection Requirements

AGENCY: Department of Labor, Employment Standards Administration, Wage and Hour Division.

ACTION: OMB approval of information collection requirements.

SUMMARY: On December 14, 2008, the Office of Management and Budget (OMB) approved under the Paperwork Reduction Act (PRA) the Department of Labor's information collection request for requirements regarding Family and Medical Leave Act regulations, as published in the **Federal Register** on November 17, 2008. The PRA requires this notice to set forth the effectiveness