govern specific domestic licenses to manufacture or transfer certain items containing byproduct material and medical use of byproduct material. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on October 29, 2007. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 18th day of September, 2007.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration.

[FR Doc. E7–18743 Filed 9–21–07; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 2007N–0264]

Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; correction.

SUMMARY: The Food and Drug Administration is correcting a direct final rule that appeared in the **Federal Register** of August 16, 2007 (72 FR 45883). That document amended the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. A proposal was published as a companion document to the direct final rule in the same issue of the **Federal Register** (August 16, 2007, 72 FR 45993). Both documents published with a typographical error in the codified section. This document corrects the error in the direct final rule. Elsewhere in this issue of the **Federal Register** we are correcting the error in the proposed rule.

DATES: This correction is effective February 19, 2008.

FOR FURTHER INFORMATION CONTACT:

For information regarding this correction: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

For information regarding the direct final rule: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–15943, appearing on page 45883, in the **Federal Register** of Thursday, August 16, 2007, the following correction is made:

§ 610.53 [Corrected]

■ 1. On page 45887, in the amendment to § 610.53 *Dating periods for licensed biological products*, in the table in paragraph (c), ''65° C'' is corrected to read ''-65° C'' everywhere it appears.

Dated: September 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18799 Filed 9–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–309F]

Designation of Oripavine as a Basic Class of Controlled Substance

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final Rule.

SUMMARY: This is a final rule issued by the Drug Enforcement Administration (DEA) designating oripavine (3-*O*-demethylthebaine or 6,7,8,14-tetradehydro-4,5-*alpha*-epoxy-6-methoxy-17-methylmorphinan-3-ol) as a basic class in schedule II of the Controlled Substances Act (CSA). Although oripavine was not previously listed in schedule II of the CSA, it has been controlled in the United States as a derivative of thebaine and, as such, is controlled as a schedule II controlled substance which includes ''Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.'' Oripavine is a derivative of thebaine, a natural constituent of opium, hence oripavine has been and continues to be, by virtue of the definition of ''narcotic drug'', a schedule II controlled substance. International control of oripavine in schedule I of the 1961 Single Convention on Narcotic Drugs (1961 Convention) during the 50th session of the Commission on Narcotic Drugs (CND) in 2007 prompted the DEA to specifically designate oripavine as a basic class of controlled substance in schedule II of the CSA.

DATES: Effective September 24, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, by e-mail, *ode@dea.usdoj.gov* or by fax, (202) 353–1263.

SUPPLEMENTARY INFORMATION:

Oripavine Control

Oripavine (3-*O*-demethylthebaine or 6,7,8,14-tetradehydro-4,5-*alpha*-epoxy-6-methoxy-17-methylmorphinan-3-ol) is the international non-proprietary name for a chemical substance which is chemically similar to thebaine. It is a phenanthrene alkaloid contained in various species of the genus *Papaver* and is a major metabolite of thebaine. Although oripavine was not previously listed in schedule II of the CSA, it has been controlled in the United States as a derivative of thebaine and, as such, is controlled under 21 U.S.C. 812(c) Schedule II (a)(1) which includes ''Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.'' Oripavine is a derivative of thebaine, a natural constituent of opium, hence oripavine has been and continues to be, by virtue of the definition of ''narcotic drug'', a schedule II controlled substance (21 U.S.C. 802(17)(A); 21 CFR 1308.12(b)(1)(17)). Oripavine is easily converted into thebaine and thebaine, in turn, is convertible into morphine and morphine derivatives. Both thebaine and morphine are opiates and are controlled under schedule I of the 1961 Single Convention on Narcotic Drugs (1961 Convention): Morphine for its abuse potential and thebaine for its convertibility into morphine derivatives.

DEA's Authority To Control Oripavine

This order is prompted by a letter dated June 27, 2007, in which the United States Government was informed by the Secretary-General of the United Nations that oripavine has been added to schedule I of the 1961 Convention. This letter was prompted by a decision at the 50th session of the CND in March 2007 to schedule oripavine under schedule I of the 1961 Convention. As a signatory Member State to the 1961 Convention, the United States is obligated to control oripavine under

national drug control legislation, i.e., the Controlled Substances Act (CSA).

Oripavine is currently controlled domestically in schedule II of the CSA as a thebaine derivative and as such, all regulations and criminal sanctions applicable to schedule II substances have been and remain applicable to oripavine. Drugs controlled in schedule II of the CSA satisfy the requirements of schedule I control under the 1961 Convention.

This action has the net effect of listing oripavine as a basic class of controlled substance in schedule II. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA registered manufacturers of oripavine who had previously been granted individual quotas for such purposes under the basic class of thebaine.

Regulatory Certifications

Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking and allow for a period of public comment prior to implementing new rules. The APA also provides, however, that agencies can be excepted from these requirements when ''the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(B).

DEA has concluded that ''good cause'' exists to promulgate this rule as a final rule rather than a proposed rule in order to be in compliance with international treaty obligations to control oripavine under the CSA, as a basic class of controlled substance in schedule II. Furthermore, DEA concludes that this procedure is unnecessary since oripavine is already subject to domestic control under schedule II as a derivative of thebaine and no additional requirements are being imposed through this action. Since DEA is without authority to revise this rule based on public comments, DEA finds that notice and opportunity for comment are unnecessary under the APA. 5 U.S.C. 553(b)(B).

Further, the APA permits an agency to make a rule effective upon the date of publication if the agency makes a finding of good cause which is published with the rule (5 U.S.C. 553(d)(3)). As oripavine is already subject to domestic control under schedule II and no additional requirements are being imposed through this action, DEA believes that delaying the effective date of this rule could cause confusion regarding the regulatory status of oripavine. Oripavine is currently controlled as a schedule II controlled substance, and this level of control does not change with this rulemaking. Accordingly, DEA finds that good cause exists to justify an immediate effective date.

Regulatory Flexibility Act

This action will not have a significant economic impact on a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601–612). At present, there are less than ten DEA registrants that are impacted by this rule. Additionally, DEA notes that these same entities currently meet the regulatory responsibilities under the CSA for schedule II as it pertains to this substance due to oripavine's control as a thebaine derivative prior to this action.

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132 Federalism

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by Section 201(d)(1) of the CSA (21 U.S.C. 811(d)(1)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, Appendix to Subpart R, Section 12, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.12 is amended by revising the table in paragraph (b)(1) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) * * *

(i) Codeine	9050
(ii) Dihydroetorphine	9334
(iii) Ethylmorphine	9190
(iv) Etorphine hydrochloride	9059
(v) Granulated opium	9640
(vi) Hydrocodone	9193
(vii) Hydromorphone	9150
(viii) Metopon	9260
(ix) Morphine	9300
(x) Opium extracts	9610
(xi) Opium fluid	9620
(xii) Oripavine	9335
(xiii) Oxycodone	9143
(xiv) Oxymorphone	9652
(xv) Powdered opium	9639
(xvi) Raw opium	9600
(xvii) Thebaine	9333
(xviii) Tincture of opium	9630

* * * * *

Dated: September 13, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–18524 Filed 9–21–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 637

[FHWA Docket No. FHWA–2006–26501]

RIN 2125–AF21

Crash Test Laboratory Requirements for FHWA Roadside Safety Hardware Acceptance

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final Rule.

SUMMARY: The FHWA is revising its regulation that establishes the general requirements for quality assurance procedures for construction on all Federal-aid highway projects on the National Highway System (NHS).[1] Specifically, the FHWA will require accreditation of laboratories that conduct crash tests on roadside hardware by an accrediting body that is recognized by the National Cooperation for Laboratory Accreditation (NACLA) or is a signatory to an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), an Asia Pacific Laboratory Accreditation Cooperation (APLAC) MRA, or another comparable accreditation body approved by FHWA. This rule will improve the agency's ability to determine that crash test laboratories are qualified to conduct and evaluate tests intended to determine the crashworthiness of roadside safety features. Laboratory accreditation is widely recognized as a reliable indicator of technical competence.

DATES: Effective October 24, 2007.

FOR FURTHER INFORMATION CONTACT: Matt Lupes, Office of Safety Design, HSSD, (202) 366–6994, Nicholas Artimovich, Office of Safety Design, HSSD, (202) 366–1331, or Raymond Cuprill, Office of the Chief Counsel, (202) 366–0791, Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document, the notice of proposed rulemaking (NPRM), and all of the comments received may be viewed online through the Document Management System (DMS) at *http://dms.dot.gov*. The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at *http://www.archives.gov* or the Government Printing Office's Web page at *http://www.gpoaccess.gov/nara.*

Background

Section 109(c) of title 23, United States Code, as amended by section 304 of the National Highway System Designation Act of 1995 (Pub. L. 104–59; 109 Stat. 188; Nov. 28, 1995), requires the Secretary, in cooperation with the State transportation departments, to approve design and construction standards on the NHS, regardless of funding source. These design standards include not only elements pertaining to the roadway itself, but also to any appurtenances installed along the roadway, such as traffic barriers (roadside and median barriers, and bridge railings), sign and luminaire supports and crash cushions.

The FHWA proposed to amend 23 CFR 637.209 by adding 637.209(a)(5) that would require all laboratories that perform crash testing for acceptance of roadside safety hardware to be accredited by an accreditation body that is recognized by NACLA or is a signatory to the APLAC MRA, ILAC MRA, or another comparable accreditation body approved by FHWA. To FHWA's knowledge, NACLA and the laboratory accreditation bodies that are members of ILAC and APLAC are the only laboratory accreditation bodies that exist. Information on accrediting bodies that are signatories to APLAC's MRA and ILAC's MRA, including estimated costs and application procedures for laboratory accreditation, can be found at their respective Web sites *http://www.aplac.org* and *http://www.ilac.org;* similar information on NACLA's accrediting bodies can be found at *http://nacla.net.* Formal accreditation assesses factors such as the technical competency of laboratory personnel, the validity of test methods, the calibration and maintenance of test equipment, and the quality assurance of calibration and test data.

Laboratory accreditation will be assessed according to the current International Standard ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration of Laboratories. The ISO/IEC 17025:2005 standard is divided into management and technical requirements that ensure the competence of the laboratory to produce valid data and results. Many other countries require organizations and testing laboratories to be accredited to the ISO/IEC 17025 standard for any test results used for establishing compliance. The FHWA acknowledges the ISO/IEC 17025:2005 standard as the benchmark for assessing the competence of the testing and calibration laboratories.

This final rule provides a 2-year phase-in period from the date of issuance to allow adequate time to prepare documentation and budgeting for formal accreditation. Based on the experience of the two accredited labs in the U.S., we estimate that adequate preparation for accreditation could vary depending on the size of the labs and could take 2 to 6 months.

Discussion of Comments Received to the Notice of Proposed Rulemaking (NPRM)

On April 9, 2007, the FHWA published a NPRM in the **Federal Register** at 72 FR 17447 to provide an opportunity for public comment on the proposed addition to 23 CFR 637.209. In response to the NPRM, the FHWA received comments to the docket from one State Transportation Agency (Minnesota) and one private company (Transport Research Laboratory). Both comments to the docket expressed support for adopting this final rule. The FHWA received no other comments on this rulemaking and therefore adopts the regulation as proposed in the NPRM.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action would not be a significant regulatory action within the meaning of Executive Order 12866 and would not be significant within the meaning of U.S. Department of Transportation regulatory policies and procedures. It is anticipated that the economic impact of this rulemaking would be minimal. Currently, two of the test laboratories in the U.S. are already accredited and this regulation has no effect on those entities. The two currently accredited

[1] The National Highway System (NHS) includes the Interstate Highway System as well as other roads important to the Nation's economy, defense, and mobility. See 23 U.S.C. 103(b). The NHS was developed by the U.S. Department of Transportation (DOT) in cooperation with the States, local officials, and metropolitan planning organizations (MPOs).