specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. We will publish notice of the objections that we have received or lack thereof in the Federal Register.

XI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.)

1. Memorandum to the File from A. Zajac, Division of Petition Review, February 27, 2015.


List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, and Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:


2. Section 73.200 is amended by revising paragraphs (b)(1) and (c)(1) to read as follows:

§ 73.200 Synthetic iron oxide.

* * * * *

(b) * * *

(1) Synthetic iron oxide for human food use shall conform to the following specifications:

Arsenic (as As), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million (ppm)).

Lead (as Pb), not more than 5 mg/kg (5 ppm).

Mercury (as Hg), not more than 1 mg/kg (1 ppm).

* * * * *

(c) * * *

(1) Synthetic iron oxide may be safely used for human food use subject to the following restrictions:

(i) In sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(ii) In soft and hard candy, mints, and chewing gum at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

* * * * *

Dated: March 17, 2015.

Susan M. Bernard,
Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–406]

Substances Temporarily Controlled Under Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; technical amendments.

SUMMARY: This final rule makes technical and conforming amendments to the Drug Enforcement Administration regulations listing substances temporarily controlled under schedule I of the Controlled Substances Act. This final rule eliminates references to 7 substances that were previously subject to temporary control, but which have since been permanently controlled under schedule I, and redesignates 23 other substances that are currently temporarily controlled under schedule I. This action makes no substantive changes to the affected regulation.

DATES: This rule is effective March 20, 2015.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.
Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all controlled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

The CSA provides the Attorney General with the authority to temporarily control a substance under schedule I for two years without regard to the requirements of 21 U.S.C. 811(b) if he/she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). If proceedings to permanently control a substance are initiated pursuant to 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary control for up to one year. 21 U.S.C. 811(h)(2). The Attorney General has delegated this authority to the Administrator of the DEA. 26 CFR 0.100.

Technical Amendments

The Synthetic Drug Abuse Prevention Act of 2012 (SDAPA) became effective on July 9, 2012. SDAPA amended the CSA by permanently controlling “cannabimimetic agents” and 26 other specific substances in schedule I. At that time, some of the 26 permanently controlled substances were temporarily controlled and listed in 21 CFR 1308.11(g), including the following substances: 1-pentyl-3-(1-naphthyl)indole (JWH–018); 1-butyryl-3-(1-naphthyl)indole (JWH–073); 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthyl)indole (JWH–200); 5-(1,1-dimethylcyclohexyl)-phenol (cannabicyclohexanol or CP–47,497 C8 homologue); 4-methyl-N-methylcathinone (mephedrone); and 3,4-methylenedioxyxyprovalerone (MDPV). On January 4, 2013, the DEA published a final rule permanently placing cannabimimetic agents and all 26 substances specified in SDAPA into schedule I (including the 6 substances noted above that were previously temporarly controlled). The substance 3,4-methylenedioxy-N-methylcathinone (methylone) was not permanently controlled through SDAPA. However, DEA temporarily controlled methylone on October 21, 2011, pursuant to 21 U.S.C. 811(h), and listed it in 21 CFR 1308.11(g)(7). On January 4, 2013, subparagraph (g) of 21 CFR 1308.11 was redesignated as subparagraph (h), and methylone was renumbered in section 1308.11(h)(1); it also inadvertently remained on the list of temporarily controlled substances in section 1308.11(h)(7). The DEA permanently controlled methylone in schedule I by a final rule published in the Federal Register on April 12, 2013. Because the above noted substances are permanently controlled in schedule I, the DEA is making technical and conforming amendments to the regulations by removing the above referenced 7 substances (JWH–018; JWH–073; CP–47,497 C8 homologue; mephedrone; MDPV; and methylone) from the list of temporarily controlled substances and redesignating the numerical order of the remaining controlled substances that are currently subject to temporary control.

Regulatory Analyses

The Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest under 5 U.S.C. 553(b)(2). This rule provides technical and conforming amendments to the DEA’s regulations and imposes no new or substantive requirement on the public or DEA registrants. As such, the DEA has determined that notice and opportunity for public comment on this rule are unnecessary. In addition, because this is not a substantive rule and as the DEA finds good cause under 5 U.S.C. 553(d)(3) for the above reasons, this final rule shall take effect upon the date of publication in the Federal Register.

Executive Orders 12866 and 13563

The Administrator certifies that this is not a significant regulatory action within the meaning of Executive Order 12866 and the principles reaffirmed in Executive Order 13563, as it makes only technical amendments to the current regulations. Such actions are exempt from review by the Office of Management and Budget (OMB).

Executive Order 12988

This rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rule does not have federalism implications warranting the application of Executive Order 13132. This rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act of 1995

This rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. The rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

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 (CRA)). 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 for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to...
the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

§ 1308.11 [Amended]

2. Amend § 1308.11 by removing paragraphs (h)(1) through (8) and redesignating paragraphs (h)(9) through (31) as paragraphs (h)(1) through (23), respectively.

Dated: March 12, 2015.
Michele M. Leonhart,
Administrator.

[FR Doc. 2015–06460 Filed 3–19–15; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0171]

Drawbridge Operation Regulation; Cerritos Channel, Long Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Commodore Schuyler F. Heim highway bridge across the Cerritos Channel, at Long Beach, CA. The deviation is necessary to allow Southern California Edison Company to perform circuit switching. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective without actual notice from March 20, 2015 to 2 a.m. on March 23, 2015. For the purposes of enforcement, actual notice will be used from 10 p.m. on March 15, 2015, until March 20, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0157], is available at http://www.regulations.gov. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For further information contact: If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 202–366–9826. If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTAL INFORMATION: California Department of Transportation has requested a temporary change to the operation of the Commodore Schuyler F. Heim highway bridge, mile 4.9, over Cerritos Channel, at Long Beach, CA. The drawbridge navigation span provides a vertical clearance of 37 feet above Mean High Water in the closed-to-navigation position and a maximum of 43 feet due to construction falsework over the channel at the bridge. The draw opens on signal; except that, from 6:30 a.m. to 8 a.m. and 3:30 p.m. to 6 p.m., Monday through Friday except Federal holidays, the draw need not be opened for the passage of vessels, as required by 33 CFR 117.147(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 10 p.m. on March 15, 2015 to 2 a.m. on March 16, 2015; and from 10 p.m. on March 22, 2015 to 2 a.m. on March 23, 2015 to allow Southern California Edison Company to switch electrical power for the bridge to another source. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is an alternate route around Terminal Island for routine and emergency navigation.

The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices of the change in operating schedule for the bridge so vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 11, 2015.

D.H. Sulouff,
District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2015–06491 Filed 3–19–15; 8:45 am]
BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0171]

Drawbridge Operation Regulation; Duwamish Waterway, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the South Park highway bridge across the Duwamish Waterway, mile 3.8, at Seattle, WA. The deviation is necessary to enable timely completion of drawbridge maintenance. This deviation allows the drawbridge to remain closed to mariners needing a full channel, double bascule leaf drawbridge opening. Vessels that only require a single leaf, half channel drawbridge opening, will be given such an opening upon signal.

DATES: This deviation is effective without actual notice from March 20, 2015 to 11:59 p.m. on March 28, 2015. For the purposes of enforcement, actual notice will be used from 12:01 a.m. on March 17, 2015, until March 20, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0171] is available at http://www.regulations.gov. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.