

occur between points in the United States, and between the United States and any foreign point, in the following types of operations:

(i) Scheduled passenger foreign air transportation.

(ii) Nonscheduled passenger foreign air transportation, if a flight attendant is a required crewmember on the aircraft as determined by the Administrator of the Federal Aviation Administration or a foreign carrier's government.

(2) Nothing in this section shall be deemed to require foreign air carriers to permit smoking aboard aircraft.

(b) A foreign government objecting to the application of paragraph (a) of this section on the basis that paragraph (a) provides for extraterritorial application of the laws of the United States may request and obtain a waiver of paragraph (a) from the Assistant Secretary for Aviation and International Affairs, provided that an alternative smoking prohibition resulting from bilateral negotiations is in effect.

§ 252.7 [Removed]

■ 7. Section 252.7 is removed.

■ 8. Section 252.8 is revised to read as follows:

§ 252.8 Extent of smoking restrictions.

The restrictions on smoking described in §§ 252.4 and 252.5 shall apply to all locations within the aircraft.

§§ 252.13 and 253.15 [Removed]

■ 9. Sections 252.13 and 253.15 are removed.

■ 10. Section 252.17 is revised to read as follows:

§ 252.17 Enforcement.

Air carriers and foreign air carriers shall take such action as is necessary to ensure that smoking by passengers or crew is not permitted where smoking is prohibited by this part, including but not limited to aircraft lavatories.

§ 252.19 [Removed]

■ 11. Section 252.19 is removed.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801 and 830

[Docket No. FDA-2011-N-0090]

Unique Device Identification System; Editorial Provisions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the Unique Device Identification (UDI) System regulation to make editorial changes. This technical amendment updates the email address associated with FDA's UDI system, which allows FDA to obtain information and offer support and assistance on medical devices through their distribution and use, ensuring consistency with the requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This change is necessary to ensure that the UDI team continues to maintain regular email communications with device labelers.

DATES: This rule is effective March 4, 2016.

FOR FURTHER INFORMATION CONTACT:

Adaeze Teme, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5574, Silver Spring, MD 20993-0002, 240-402-0768.

SUPPLEMENTARY INFORMATION: FDA is updating the UDI email address in the following regulations that set forth the procedures for notifying the Agency when: (1) Requesting an exception from or alternative to a unique device identifier requirement (§ 801.55 (21 CFR 801.55)); (2) requesting continued use of legacy FDA identification numbers assigned to devices (§ 801.57 (21 CFR 801.57)); and (3) applying for accreditation as an issuing Agency (§ 830.110 (21 CFR 830.110)).

Specifically, the Agency is removing an old email address and replacing it with a new one, thereby maintaining consistency with the requirements of the FD&C Act (21 U.S.C. 321 *et seq.*).

In the **Federal Register** of September 24, 2013 (78 FR 58786), FDA issued a final rule to establish a system to adequately identify devices through distribution and use. The rule required the label of medical devices to include a UDI, except where an exception or alternative applies. The labeler must

submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID). The final rule incorporated a direct avenue for the labeler to communicate with FDA's GUDID via a UDI email address. This rule updates §§ 801.55(b)(2), 801.57(c)(2), and 830.110(a) by replacing the old email address with a new one.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 830

Administrative practice and procedure, Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801 and 830 are amended as follows:

PART 801—LABELING

■ 1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 2. In § 801.55, revise paragraph (b)(2) to read as follows:

§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.

* * * * *

(b) * * *

(2) In all other cases, by email to: *GUDIDSupport@fda.hhs.gov*, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993-0002.

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■ 3. In § 801.57, revise the second sentence of paragraph (c)(2) to read as follows:

§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

* * * * *

(c) * * *

(2) * * * * A request for continued use of an assigned labeler code must be submitted by email to: *GUDIDSupport@fda.hhs.gov*, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993-0002.

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PART 830—UNIQUE DEVICE IDENTIFICATION

■ 4. The authority citation for 21 CFR part 830 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

■ 5. In § 830.110, revise paragraph (a)(1) to read as follows:

§ 830.110 Application for accreditation as an issuing agency.

(a) * * * (1) An applicant seeking initial FDA accreditation as an issuing agency shall notify FDA of its desire to be accredited by sending a notification by email to: GUDIDSsupport@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993–0002.

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Dated: February 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04707 Filed 3–3–16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–386]

Schedules of Controlled Substances: Extension of Temporary Placement of 10 Synthetic Cathinones in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to extend the temporary schedule I status of 10 synthetic cathinones pursuant to the temporary scheduling provisions of the Controlled Substances Act. The 10 substances are: 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); *alpha*-pyrrolidinopentiophenone (*α*-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); and *alpha*-

pyrrolidinobutiophenone (*α*-PBP) [hereinafter 4-MEC, 4-MePPP, *α*-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and *α*-PBP, respectively], including their optical, positional, and geometric isomers, salts, and salts of isomers. The current final order temporarily placing 4-MEC, 4-MePPP, *α*-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and *α*-PBP into schedule I is in effect through March 6, 2016. This final order will extend the temporary scheduling of 4-MEC, 4-MePPP, *α*-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and *α*-PBP for one year, or until the permanent scheduling action for these 10 substances is completed, whichever occurs first.

DATES: This final order is effective March 4, 2016.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (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 purpose of this action. 21 U.S.C. 801–971. The DEA published 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 ensuring an adequate supply is available 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, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other 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 scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated her scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

On March 7, 2014, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the 10 synthetic cathinones 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); *alpha*-pyrrolidinopentiophenone (*α*-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); and *alpha*-pyrrolidinobutiophenone (*α*-PBP) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 12938. That final order was effective on the date of publication, and was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these ten synthetic cathinones was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the temporary control of these substances expires two years from the effective date of the scheduling order, or on March 6, 2016. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect