PART 152—[REMOVED]

■ Therefore, for the reasons discussed in the preamble, under the Federal Food, Drug and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration removes 21 CFR part 152.

Dated: February 27, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–04598 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807 and 814

[Docket No. FDA–2024–N–1052]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending certain medical device regulations to update a citation for information collection and conform the regulatory provisions to the Federal Food, Drug, and Cosmetics Act (FD&C Act). The rule does not impose any new requirements on affected parties. This action is editorial in nature to correct errors and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is March 15, 2024.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5837.

SUPPLEMENTARY INFORMATION:

I. Background

As a part of this technical amendment, FDA is making changes to 21 CFR parts 807 and 814 to update a citation for information collection and to conform the regulatory provisions to the FD&C Act to ensure accuracy and clarity in the Agency's medical device regulations. The changes published in this notice are nonsubstantive and editorial in nature.

On December 29, 2022, Congress enacted the Food and Drug Omnibus Reform Act of 2022, Title III of 131 Division FF of the Consolidated Appropriations Act, 2023 (FDORA) (Pub. L. 117–328), which added and amended various sections of the FD&C Act. Section 3308 of FDORA added section 515C of the FD&C Act (21 U.S.C. 360e–4). Section 515C provides FDA with express authority to approve or clear predetermined change control plans (PCCPs) for devices requiring premarket approval applications (PMAs) under section 515 of the FD&C Act (21 U.S.C. 360e) or premarket notification under section 510(k) of the FD&C Act (510(k)) (21 U.S.C. 360). Under section 515C manufacturers will not need to submit PMAs, including a supplemental application, or a new 510(k) as long as the change is consistent with a PCCP approved or cleared by FDA.

II. Description of the Technical Amendments

We are amending 21 CFR 807.81(b) and 814.39(b) to include predetermined change control plans cleared or approved, respectively, under 515C consistent with the statutory language in section 515C of the FD&C Act. The regulation, 21 CFR 807.87(m), is being revised to make a nonsubstantive editorial change to remove the incorrect information collection requirement citation. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action under the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553 of the APA generally exempts ''rules of agency organization, procedure, or practice'' from proposed rulemaking (*i.e.,* notice and comment rulemaking (5 U.S.C. 553(b)(A)). Rules are also exempt when an agency finds ''good cause'' that notice and comment rulemaking procedures would be ''impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)).

FDA has determined that this rulemaking meets the APA's notice and comment exemption requirements under 5 U.S.C. 553(b)(3)(B). All the revisions in this rule are technical or nonsubstantive changes. Some of these revisions update the language in certain regulations to be consistent with the FD&C Act. The balance of these revisions updates an incorrect citation for information collection. Such technical, nonsubstantive changes are ''a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012) (quotation marks and citation omitted). FDA accordingly for good cause finds that notice and public procedure thereon are unnecessary for these amendments.

The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). An effective date 30 or more days from the date of publication is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties, and affected parties do not need time to ''adjust to the new regulation'' before the rule takes effect. *Am. Federation of Government Emp., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981). Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 807 and 814 are amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 1. The authority citation for part 807 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360e–4, 360i, 360j, 360bbb–8b, 371, 374, 379k–1, 381, 393; 42 U.S.C. 264, 271.

■ 2. In § 807.81, revise paragraph (b)(1) to read as follows:

§ 807.81 When a premarket notification submission is required.

* * * * *

(b)(1) A premarket notification under this subpart is not required for a device for which:

(i) A premarket approval application under section 515 of the act, or for which a petition to reclassify under

section 513(f)(2) of the act, is pending before the Food and Drug Administration, or

(ii) There is a predetermined change control plan (PCCP) cleared under section 515C of the act, provided that the change is consistent with the PCCP.

* * * * *

§ 807.87 [Amended]

■ 3. Amend § 807.87 by removing the phrase ''(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0281)'' that appears after paragraph (m).

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 4. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

■ 5. In § 814.39, revise paragraph (b) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post approval periodic reports required as a condition to approval of the device, *e.g.,* an editorial change in labeling which does not affect the safety or effectiveness of the device, or if the change is consistent with a predetermined change control plan (PCCP) approved under section 515C of the act.

* * * * *

Dated: March 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05473 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1245]

Schedules of Controlled Substances: Placement of 2-Methyl AP–237 in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing 1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one (commonly known as 2-methyl AP–237), including its optical and geometric isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle 2-methyl AP–237.

DATES: Effective April 15, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (Commission) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (Secretary-General), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

In a letter dated November 24, 2022, the Director-General of the World Health Organization recommended to the Secretary-General of the United Nations that 2-methyl AP–237 be placed in Schedule I of the Single Convention, as this substance has an opioid mechanism of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* 2-methyl AP–237 is similar to drugs such as isotonitazene) and has dependence and abuse potential. On May 17, 2023, the United States Government was informed by the Secretariat of the United Nations, by letter, that during its 66th session in March 2023, the Commission voted to place 2-methyl AP–237 in Schedule I of the Single Convention (CND Mar/66/1).

2-Methyl AP–237

2-Methyl AP–237 has a pharmacological profile similar to other classical opioids such as fentanyl (schedule II), morphine (schedule II) and heroin (schedule I), which act as mu-opioid receptor agonists. Because of the pharmacological similarities of 2-methyl AP–237 to the aforementioned opioids, 2-methyl AP–237 presents a high risk of abuse and has negatively affected users and communities. According to the DEA Toxicology Testing Program (DEA TOX) [1] and a recent publication,[2] the abuse of 2-methyl AP–237 has been associated with at least seven fatalities in the United States between February 2020 and July 2023. The identification of this substance in post-mortem cases is a serious concern to public safety.

In June 2019, 2-methyl AP–237 emerged on the United States illicit drug market as evidenced by its identification in drug seizures.[3] Law enforcement

[1] The DEA Toxicology Testing Program (DEA TOX) was initiated in response to the ongoing novel synthetic drug abuse epidemic. This program provides toxicology data on synthetic drugs from biological samples that may not be routinely identified, which are generated from drug overdose victims. Data queried on 8/7/2023.

[2] Fogarty, MF, Vandeputte, MM, Krotulski, AJ, Walton, SE, Stove, CP, and Logan, BK (2022). Toxicological and pharmacological characterization of novel cinnamylpiperazine synthetic opioids in humans and in vitro including 2-methyl AP–237 and AP–238. Archives of Toxicology 96:1701–1710.

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive

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