TABLE 1—INTERNAL THERAPEUTIC MASSAGER RISKS AND MITIGATION MEASURES—Continued

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbial contamination from reusable components</td>
<td>Labeling.</td>
</tr>
<tr>
<td>Vaginal/rectal cross-contamination</td>
<td>Labeling.</td>
</tr>
<tr>
<td>Overstretching/weakness of the anal sphincter and vagina</td>
<td>Non-clinical performance testing, and Labeling.</td>
</tr>
<tr>
<td>Mechanical failure during use</td>
<td>Non-clinical performance testing.</td>
</tr>
<tr>
<td>User error</td>
<td>Labeling.</td>
</tr>
<tr>
<td>Electrical shock</td>
<td>Electrical safety testing, and Labeling.</td>
</tr>
<tr>
<td>Electromagnetic incompatibility</td>
<td>Electromagnetic compatibility testing, and Labeling.</td>
</tr>
<tr>
<td>Software failure</td>
<td>Software verification, validation, and hazard analysis.</td>
</tr>
</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, internal therapeutic massagers are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We believe this may be such a device. The notice of intent to exempt the device from premarket notification requirements is published elsewhere in this issue of the Federal Register.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. Add an authority citation for part 890 to read as follows:


2. Add § 890.5670 to subpart F to read as follows:

§ 890.5670 Internal therapeutic massager.

(a) Identification. A hand-held internal therapeutic massager device is a prescription device intended for medical purposes to manually provide direct pressure applied to localized areas of pain or tenderness in the myofascial tissue associated with chronic pelvic pain syndromes. The device is inserted rectally or vaginally and provides quantitative feedback to the user of the applied force to the target tissue.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Labeling must include adequate directions for use.

(2) Non-clinical performance testing must demonstrate electromagnetic compatibility (EMC), electrical safety and mechanical safety.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical durability; and

(ii) Accuracy of the feedback mechanism.

(4) Software verification, validation, and hazard analysis must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

Dated: October 21, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019–23304 Filed 10–24–19; 8:45 am]
maintains the placement of the substances cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropeneacarbamimide), methoxyacetyl fentanyl (2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide), ortho-fluorofentanyl (N-(1-phenethylpiperidin-4-yl)-N-(1-phenethylpiperidin-4-yl)-propionamide), and para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide), including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, 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 continues to impose 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, cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl.

DATES: Effective October 25, 2019.

FOR FURTHER INFORMATION CONTACT:
Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201(d)(1) of the Controlled Substances Act (CSA) (21 U.S.C. 811(d)(1)) states that, 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 shall 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 [section 201(a) (21 U.S.C. 811(a)] or section [202(b) (21 U.S.C. 812(b)]) of the Act] and without regard to the procedures prescribed by [section 201 (a) and (b) (21 U.S.C. 811(a) and (b)).” If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs (1961), then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control the substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

Background

On May 23, 2019, the Secretary-General of the United Nations send a letter to the Secretary of State of the United States advising him that during the 62nd session of the Commission on Narcotic Drugs, cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl were added to Schedule I of the Single Convention on Narcotic Drugs (1961). This letter was prompted by a decision at the 62nd session of the Commission on Narcotic Drugs in March 2019 to schedule cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl under Schedule I of the Single Convention on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

Cyclopropyl Fentanyl, Methoxyacetyl Fentanyl, ortho-Fluorofentanyl, and para-Fluorobutyryl Fentanyl

Cyclopropyl fentanyl (83 FR 469, January 4, 2018), methoxyacetyl fentanyl and ortho-fluorofentanyl (82 FR 49504, October 26, 2017), and para-fluorobutyryl fentanyl (83 FR 4580, February 1, 2018) were temporarily controlled in schedule I of the CSA upon finding that they pose an imminent hazard to the public safety. These substances share pharmacological profiles similar to morphine, fentanyl, and other synthetic opioids which act as µ-opioid receptor agonists. For this reason, cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl are abused for their opioid-like effects. Law enforcement and public health reports demonstrate the illicit use and distribution of these substances, which are similar to that of heroin and prescription opioid analgesics.

Cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl were identified in law enforcement encounters in the United States. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state and local forensic laboratories across the country. According to NFLIS,1 cyclopropyl fentanyl (first reported in 2016) was identified in 2,461 exhibits submitted to forensic laboratories, methoxyacetyl fentanyl (first reported in 2017) was identified in 1,718 exhibits, ortho-fluorofentanyl (first reported in 2016) was identified in 13 exhibits, and para-fluorobutyryl fentanyl (first reported in 2015) was identified in 309 exhibits.

The DEA is not aware of any claims or any medical or scientific literature suggesting that cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, or para-fluorobutyryl fentanyl have a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services (HHS) advised the DEA, by letters dated September 6, 2017 (cyclopropyl fentanyl), July 14, 2017 (methoxyacetyl fentanyl), June 9, 2017 (ortho-fluorofentanyl), and November 8, 2017 (para-fluorobutyryl fentanyl) that there were no investigational new drug applications or approved new drug applications for these substances. The DEA requested that HHS conduct a scientific and medical evaluation and a scheduling recommendation for methoxyacetyl fentanyl and ortho-fluorofentanyl (by letter dated April 18, 2018) and cyclopropyl fentanyl and para-fluorobutyryl fentanyl (by letter dated November 5, 2018). Regardless of these requests and any potential responses from HHS, the DEA is not required under 21 U.S.C. 811(d)(1) to make any findings otherwise required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). The Acting Administrator advised HHS, by letter dated September 6, 2019, that the DEA no longer requires scientific and medical evaluations and scheduling recommendations for cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl. These evaluations are no longer required due to the placement of these substances in Schedule I of the Single Convention on Narcotic Drugs (1961) in March 2019. Therefore, consistent with the framework of 21 U.S.C. 811(d), the DEA concludes that cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl have no currently accepted medical use in treatment in the United States and are most

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1 NFLIS was queried on June 7, 2019. Data are still being collected for January 2019—June 2019 due to the normal lag period for labs reporting to NFLIS.
appropriately placed in schedule I of the CSA, the same schedule in which they currently reside. Further, while the DEA temporarily scheduled these substances under 21 CFR 1308.11(h), a paragraph reserved for the temporary listing of substances subject to emergency scheduling, this order moves these substances to 21 CFR 1308.11(b). As explained above, because control is required under the Single Convention on Narcotic Drugs (1961), the DEA will not be initiating regular rulemaking proceedings to schedule these substances pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States’ obligations under the Single Convention on Narcotic Drugs (1961) and because cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl have no currently accepted medical use in treatment in the United States, the Acting Administrator of the DEA has determined that these substances should remain in schedule I of the CSA.

Requirements for Handling

Cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl have been controlled as schedule I controlled substances since January 4, 2018, October 26, 2017, October 26, 2017, and February 1, 2018, respectively. With publication of the final order contained in this document, cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl remain subject to the CSA’s schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, conduct of instructional activities, and possession of schedule I controlled substances, including the following:

1. Registration. Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. Disposal of stocks. Cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. Security. Cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl are subject to schedule I security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93.

4. Labeling and packaging. All labels, labeling, and packaging for commercial containers of cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and must be in accordance with 21 CFR part 1302.

5. Quota. A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 is required to manufacture cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl.

6. Inventory. Every DEA registrant who possesses any quantity of cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl was required to keep an inventory of all stocks of these substances on hand as of January 4, 2018, October 26, 2017, October 26, 2017, and February 1, 2018, respectively, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. Records and Reports. DEA registrants must maintain records and submit reports with respect to cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. Order Forms. All DEA registrants who distribute cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.


10. Liability. Any activity involving cyclopropyl fentanyl, methoxyacetyl fentanyl, ortho-fluorofentanyl, and para-fluorobutyryl fentanyl not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Order 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in Executive Order 13563 (Improving Regulation and Regulatory Review), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This order is not an Executive Order 13771 regulatory action.

Executive Order 12998, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12998 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, Federalism

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of Executive Order 13175. The action 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.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, 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 or procedures otherwise required for scheduling actions. Id.

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States’ obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute “rule making” under 5 U.S.C. 551(5), this
action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)’s requirement that the United States comply with its obligations under the specified international agreements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This action is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This order 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 enterprises to compete with foreign based enterprises in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted a copy of this final order 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, the DEA 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), 956(b), unless otherwise noted.

2. In §1308.11:
   a. redesignate paragraphs (b)(51) through (b)(66) as (b)(55) through (70);
   b. redesignate paragraphs (b)(41) through (b)(50) as (b)(43) through (52);
   c. redesignate paragraphs (b)(22) through (40) as (b)(23) through (41);
   d. add new paragraphs (b)(22), (42), (53), and (54); and
   e. remove and reserve paragraphs (b)(19), (21), (22), and (24).

The additions read as follows:

§1308.11 Schedule I.
   * * * * *
   (b) * * *
   (22) Cyclopropyl fentanyl [N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide] 9845
   * * * * *
   (42) Methoxyacetyl fentanyl [2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide] 9825
   * * * * *
   (53) ortho-Fluorofentanyl [N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide]; other name: 2-fluorofentanyl] 9816
   (54) para-Fluorobutyryl fentanyl [N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramidie] 9823
   * * * * *

Dated: October 19, 2019.

Uttam Dhillon,
Acting Administrator.

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE
Office of the Secretary

32 CFR Part 314

[Docket ID: DOD–2019–OS–0041]

RIN 0790–AK60

AGENCY: Defense Advanced Research Projects Agency, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This final rule removes DoD’s regulation concerning the Defense Advanced Research Projects Agency (DARPA) Privacy Program. On April 11, 2019, the DoD published a revised DoD-level Privacy Program rule, which contains the necessary information for an agency-wide Privacy Program regulation under the Privacy Act and now serves as the single Privacy Program rule for the Department. That revised Privacy Program rule also includes all DoD component exemption rules. Therefore, this regulation is now unnecessary and may be removed from the CFR.

DATES: This rule is effective on October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Brian Eshenbrenner at 703–526–6631.

SUPPLEMENTARY INFORMATION: DoD now has a single DoD-level Privacy Program rule at 32 CFR part 310 (84 FR 14728) that contains all the codified information required for the Department. The DARPA Privacy Program regulation at 32 CFR part 314, last updated on November 14, 1991 (56 FR 57802), is no longer required and can be removed.

It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest because it is based on the removal of policies and procedures that are either now reflected in another CFR part, 32 CFR part 310, or are publically available on the Department’s website. To the extent that DARPA internal guidance concerning the implementation of the Privacy Act within DARPA is necessary, it will continue to be published in DARPA Instruction 78, “Privacy and Civil Liberties,” and referenced under DARPA’s respective Privacy and Civil Liberties Programs at https://www.darpa.mil.

This rule is one of 20 separate component Privacy rules. With the finalization of the DoD-level Privacy rule at 32 CFR part 310, the Department eliminated the need for this component Privacy rule, thereby reducing costs to the public as explained in the preamble of the DoD-level Privacy rule published on April 11, 2019, at 84 FR 14728–14811.

This rule is not significant under Executive Order (E.O.) 12866, “Regulatory Planning and Review.” Therefore, E.O. 13771, “Reducing Regulation and Controlling Regulatory Costs,” does not apply.

List of Subjects in 32 CFR Part 314
Privacy.

PART 314—[REMOVED]

Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 314 is removed.

Dated: October 22, 2019.

Shelly E. Finke,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P