

Manager, International Section, Transport Standards Branch, FAA; or the EASA; or Airbus's EASA DOA: Accomplish repetitive SDIs within the compliance time defined in those repair instructions for repetitive SDIs. If no compliance time is identified in the repair instructions for repetitive SDIs, accomplish the repetitive SDIs required by paragraph (i)(2) of this AD at the compliance times defined in table 4 to paragraphs (i)(2) and (l) of this AD.

**(m) No Terminating Action**

Modification or repair of an airplane, as specified in paragraph (j) or (k) of this AD, does not constitute terminating action for the repetitive inspections required by this AD, unless it is specified otherwise in a repair method approved by the Manager, International Section, Transport Standards Branch, FAA; or the EASA; or Airbus's EASA DOA.

**(n) Reporting Requirement**

Submit a report of the findings (both positive and negative) of the inspections required by paragraphs (i) and (j) of this AD to "Airbus Service Bulletin Reporting Online Application" on Airbus World (<https://w3.airbus.com/>), at the applicable time specified in paragraph (n)(1) or (n)(2) of this AD.

(1) If the inspection was done on or after the effective date of this AD: Report within 30 days after that inspection.

(2) If the inspection was done before the effective date of this AD: Report within 30 days after the effective date of this AD.

**(o) Other FAA AD Provisions**

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Section, send it to the attention of the person identified in paragraph (p)(2) of this AD. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: Except as specified in paragraph (k) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified

as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(4) *Reporting Requirements*: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately [XX] per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

**(p) Related Information**

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017-0099, dated June 8, 2017, for related information. This MCAI may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1102.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office-EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); internet <http://www.airbus.com>. You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 22, 2017.

**Jeffrey E. Duven,**

*Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2017-26622 Filed 12-12-17; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 15**

[Docket No. FDA-2017-N-6502]

**Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation; Public Hearing; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing a public hearing entitled, "Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation." The purpose of the public hearing is to receive stakeholder input on how FDA might, under its Risk Evaluation and Mitigation Strategy (REMS) authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.

**DATES:** The public hearing will be held on January 30, 2018, from 8:30 a.m. to 4:30 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to attend, or to present at, the public hearing must register by January 16, 2018. Electronic or written comments will be accepted after the public hearing until March 16, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public hearing will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 B and C), Silver Spring, MD 20993-0002. Entrance for public hearing participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered.

*Electronic Submissions*

Electronic comments must be submitted on or before March 16, 2018. The <https://www.regulations.gov>

electronic filing system will accept comments until midnight Eastern Time at the end of March 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked, or the delivery service acceptance receipt is, on or before that date.

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-6502 for "Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation; Public Hearing; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Kathleen Davies, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 2310, Silver Spring, MD 20993, 301-796-2205, [kathleen.davies@fda.hhs.gov](mailto:kathleen.davies@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On May 23, 2017, the FDA Commissioner announced the establishment of an Opioid Policy Steering Committee (Steering Committee) to explore and develop additional approaches or strategies FDA could consider using to combat the opioid crisis. Given the unprecedented nature of the opioid crisis and the role of prescription opioids in the crisis, the Steering Committee is considering novel ways to reduce the number of new cases

of addiction while continuing to ensure the benefits of opioid products outweigh their risks.

Recent studies suggest that prescriptions for opioid analgesics are frequently dispensed for a number of tablets that exceed those needed for adequate pain control, particularly for acute pain. The Steering Committee is considering whether current prescribing patterns are contributing to the development of new addiction in patients, and whether the excess unused pills are a gateway to misuse, abuse, and addiction among family members and others who might have access to the unused pills. Therefore, the Steering Committee is exploring, by means of FDA's REMS authorities, the option of facilitating appropriate prescribing by requiring sponsors to implement a prescriber intervention at the point when the prescriber determines an opioid analgesic prescription is necessary for a patient. For example, a REMS could impact prescribing by requiring that sponsors ensure that prescribers provide specific documentation for a prescription above a specified amount, such as a statement that the quantity prescribed is medically necessary for the patient. The documentation requirement would not be intended to prevent access for patients in whom chronic use of opioid analgesics is the most appropriate therapy. Instead, it would be designed to ensure that prescribers consider whether the amount prescribed is appropriate for the patient and, if above the specified amount, document that necessity. The Steering Committee's view is that one way sponsors could implement this type of prescribing documentation requirement is through an electronic system at the point of prescribing (*i.e.*, incorporated into the prescriber's workflow) to minimize the burden on patient access and on the health care delivery system. Thus, the Steering Committee is interested in exploring evidence-based approaches that would encourage electronic prescribing as a mechanism for the prescriber to provide documentation of a safe-use condition (*e.g.*, that the quantity prescribed is medically necessary for the patient) before the drug is dispensed by the pharmacy. The Steering Committee also seeks input from the public on alternative REMS models or approaches for consideration.

##### II. Topics for Discussion at the Public Hearing

In this public hearing, FDA seeks stakeholder input on new approaches to promote the safe use of opioid analgesics using FDA's REMS

authorities. FDA is seeking feedback from a broad group of stakeholders, both private and public, who are working on the challenges of improving pain management while addressing the opioid epidemic. The Agency is also particularly interested in ensuring that any REMS intervention minimizes the burden on patient access and, to the extent practicable, on the health care delivery system. Relevant questions for consideration are provided below.

#### *Prescriber Documentation*

Many REMS programs rely on pharmacies to verify that required safe-use conditions have been documented prior to dispensing a drug product. One alternative approach under consideration would require sponsors to ensure that prescribers follow specific requirements outlined in the REMS for each opioid analgesic prescription for a quantity above a specified amount. This approach could involve use of an electronic system (e.g., electronic prescribing integrated into a prescriber's workflow) that would require prescribers to specifically document the medical necessity of the quantity prescribed for a particular patient. This documentation would be verified before the prescription reaches the pharmacy. For prescribers who intend to prescribe below the specified amount, no additional documentation of medical necessity or electronic prescription would be required.

1. If a REMS were to specify threshold drug amounts for opioid analgesic prescriptions above which prescribers would be required to provide additional documentation of medical necessity, what should the amounts be and how should they be determined for various clinical indications? What data are there to support such amounts? What additional data would be useful?

2. If such measures were required, how should prescribers be made aware of them? Within the Agency's statutory REMS authority, how should the Agency require sponsors to ensure compliance with them? How should the Agency require sponsors to assess their effect in reducing misuse, abuse, and new addictions?

#### *Additional REMS Approaches*

Health care providers generally have the capability to access state prescription drug monitoring program (PDMP) data that include patient prescription history and prescribing patterns. PDMPs are separately managed and maintained by the individual states, which may result in disparate data elements and data sharing challenges. Additionally, review of PDMP data

requires health care providers to access a database that may not be integrated into their workflow.

Either in conjunction with, or separate from, the prescriber intervention approach discussed above, the Steering Committee is considering whether to require sponsors to create a system that would leverage a nationwide database to be more effective in helping health care providers identify potential misuse and abuse (e.g., doctor shopping) and facilitate safe use of opioid analgesics (e.g., real-time identification of potential harmful drug-drug combinations). Such an approach could be integrated into the health care provider's workflow to minimize burden on the health care system.

3. The Steering Committee requests input from the public on whether, in addition to, or in conjunction with the above described prescriber intervention, and to the extent consistent with its statutory authority, the Agency should consider requiring sponsors to create a system that utilizes a nationwide prescription history database to facilitate safe use of opioid analgesics.

4. If this approach were adopted, how should the Agency require sponsors to assess the impact of such requirements?

#### *Additional Considerations*

The Steering Committee acknowledges that the approaches described above emphasize specific components within the opioid prescribing pathway and might not address other areas where misuse and abuse may be occurring. The Steering Committee seeks input from the public on additional approaches the Agency may consider, within its statutory authority, to reduce misuse, abuse, and addiction associated with opioid analgesics.

5. The proposed Opioid Analgesics REMS includes a Medication Guide and a Patient Counseling Document to educate patients. It also includes a *Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain* that contains information on counseling patients and caregivers about the safe use of opioid analgesics. Consistent with its statutory authority, should FDA require sponsors to take additional measures to ensure that health care providers, their patients, and patient caregivers and family members are educated on safe storage and disposal and the risks of misuse, abuse, and addiction associated with opioid analgesics (e.g., a public health campaign targeted at these groups)?

6. Should the Agency consider additional measures intended to improve the safety of patient storage and handling of opioid analgesics?

7. How might use of unit-of-use packaging play a role in encouraging appropriate prescribing of opioid analgesics?

8. Should the Agency require sponsors to create a mechanism by which patients could return unused pills, and if so, to whom?

### **III. Participating in the Public Hearing**

*Registration:* The FDA Conference Center at White Oak is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend, either in person or by webcast (see *Streaming Webcast of the Public Hearing*), and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments at <https://www.eventbrite.com/e/opioid-policy-steering-committee-tickets-39490940466> by January 16, 2018, and provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will notify registered presenters of their scheduled presentation times. Time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation (.DOC, .DOCX, .PPT, .PPTX, .XLS, .XLSX, .PDF formats preferred) to [kathleen.davies@fda.hhs.gov](mailto:kathleen.davies@fda.hhs.gov) on or before January 22, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public hearing. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and any other background materials will be made available 3 days before the hearing at <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm>.

If you need special accommodations due to a disability, please contact Kathleen Davies at least 7 days before the hearing.

**Streaming Webcast of the Public Hearing:** This public hearing will also be webcast for those unable to attend in person. To join the hearing via the webcast, please go to <https://collaboration.fda.gov/opsc>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### IV. Notice of Public Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner and the relevant centers/offices. Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section V). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: December 4, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-26785 Filed 12-11-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-475]

#### Schedules of Controlled Substances: Temporary Placement of Seven Fentanyl-Related Substances in Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Proposed amendment; notification of intent.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule seven fentanyl-related substances in schedule I. These seven substances are: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide (valeryl fentanyl), *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*para*-fluorobutyryl fentanyl), *N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*para*-methoxybutyryl fentanyl), *N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (*para*-chloroisobutyryl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide (isobutyryl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentane carboxamide (cyclopentyl fentanyl), and *N*-(2-fluorophenyl)-2-methoxy-*N*-(1-phenethylpiperidin-4-yl)acetamide (ocfentanil). This action is based on a finding by the Administrator that the placement of these seven synthetic opioids in schedule I of the Controlled Substances Act (CSA) is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I controlled substances under the CSA on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of these synthetic opioids.

**DATES:** December 13, 2017.

**ADDRESSES:** The DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at [www.regulations.gov](http://www.regulations.gov) under Docket Number DEA-475.

**FOR FURTHER INFORMATION CONTACT:**

Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:** This notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) to add valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil to schedule I of the Controlled Substances Act.<sup>1</sup> The temporary scheduling order will be published in the **Federal Register**, but will not be issued before January 12, 2018.

#### Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he 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); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

<sup>1</sup> Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.