RPG CROSS-SITE EVALUATION ANNUALIZED BURDEN ESTIMATES—Continued

Data collection activity	Total number of respondents	Number of responses per respondent (each year)	Average burden hours per response (in hours)	Estimated total burden hours	Total annual burden hours
Partner survey	135	.33	0.42	56.3	18.8
Enrollment, client and service data					
Semi-annual progress reports	27	2	16.5	2,673	891
Case enrollment data	81	43	0.25	2,612.3	870.8
Case closure	81	43	0.017	174.2	58.1
Case closure—prenatal	81	33	0.017	133.7	44.6
Service log entries	162	2,288	0.03	37,065	12,355
Outcome and impact data					
Administrative Data:					
Obtain access to administrative data	27	1	42.6	3,450.6	1150.2
Report administrative data	27	2	144	23,328	7,776
Standardized instruments:					
Review and adopt reporting templates	27	.33	8	216	72
Data entry for standardized instruments	27	130	1.25	13,162.5	4,387.5
Review records and submit	27	2	25	4,050	1,350
Data entry for comparison study sites (22 grantees)	22	130	1.25	10,725	3,575
Estimated Total Burden Hours				97,827	32,609

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Children's Bureau within the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to Administration for Children and Families, Office of Administration, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–22020 Filed 10–9–18; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3685]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB–FUBINACA; ADB–CHMINACA; Cyclopropyl Fentanyl; Methoxyacetyl Fentanyl; para-Fluoro Butyrfentanyl; Tramadol; Pregabalin; Cannabis Plant and Resin; and Eight Additional Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 16 drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (the CSA).

DATES: Submit either electronic or written comments by October 31, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before (enter date), 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 31, 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.

Electronic Submissions

Submit electronic comments in the following way:

- *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–2018–N–3685 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB–FUBINACA; FUB–AMB(MMB–FUBINACA_AMB–FUBINACA); ADB–CHMINACA; CUMYL–4CN–BINACA; Cyclopropyl Fentanyl; Methoxyacetyl Fentanyl; *Ortho*-Fluorofentanyl; *Para*-Fluoro Butyrfentanyl; *Para*-Methoxybutyrfentanyl; *N*-Ethylnorpentylone; Tramadol; Pregabalin; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; 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: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993–0002, 301–796–3156, email: *james.hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (the U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Paragraph (d)(2)(A) of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (non-relevant text removed):

Ref.: C.L.26.2018

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of informing that the 41th Expert Committee on Drug Dependence (ECDD) will meet in Geneva from 12 to 16 November 2018. The 41th ECDD will convene to review psychoactive substances on their potential to cause dependence, abuse and harm to health, and their potential therapeutic applications. WHO will make recommendations to the UN Secretary-General on the need for and level of international control of these substances.

Member States are invited to collaborate, as in the past, in this process by providing pertinent information as requested in the questionnaire and concerning substances under review. At its 126th session in January 2010, the Executive Board approved the publication ''Guidance on the WHO review of psychoactive substances for international control'' (EB126/2010/REC1, Annex 6) which requires the Secretariat to request relevant information from Ministers of Health in Member States to prepare a report for submission to the ECDD.

For this purpose, a questionnaire was designed to gather information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation. A list of substances for which Member States will receive questionnaires is attached.

Kindly note that Member States who submitted questionnaire responses that were reviewed at the 40th ECDD on cannabis and cannabis-related substances will not be requested to re-submit questionnaires for those substances for the 41st ECDD. However, if Member States would like to amend their responses or submit additional information on cannabis and cannabis-related substances, it is requested that they inform the Secretariat.

It would be appreciated if a person from the Ministry of Health could be designated as the focal point responsible for coordinating answers to the questionnaires. A list of focal

points designated by Member States for the 40th ECDD in June 2018 is attached. It is requested that if a focal point's contact details including email address are to be added or amended, that Member States inform the Secretariat by 17 September 2018. Any additions or amendments to focal point designations should be emailed to *ecddsecretariat@who.int.*

If no additions or amendments to focal point details are made by this date, the focal point from 2018 will be approached by the Secretariat for questionnaire completion. Where there is a competent National Authority under the International Drug Control Treaties, it is kindly requested that the questionnaires be completed in collaboration with such body.

Once the Secretariat has received the contact details, focal points will be given further instructions and direct access to an online questionnaire. The questionnaires will be analysed by the Secretariat and prepared as a report that will be shared with the Committee for review.

Member States are also encouraged to provide any additional relevant information (unpublished or published) that is available on these substances to: *ecddsecretariat@who.int.* This information will be an invaluable contribution to the ECDD and all submissions will be treated as confidential.

The WHO takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.
GENEVA, 21 August 2018

Attachment:

41st WHO Expert Committee on Drug Dependence

Member State Questionnaire Substances

SYNTHETIC CANNABINOIDS

ADB–FUBINACA
FUB–AMB (MMB–FUBINACA, AMB–FUBINACA)
ADB–CHMINACA
CUMYL–4CN–BINACA

FENTANYLS

Cyclopropyl Fentanyl
Methoxyacetyl Fentanyl
Ortho-Fluorofentanyl
Para-Fluoro Butyrfentanyl
Para-Methoxybutyrfentanyl

(METH)CATHINONE

N-Ethylnorpentylone

MEDICINES

Tramadol
Pregabalin

FDA has verified the website addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time. Access to view the WHO questionnaire can be found at *http://www.who.int/medicines/access/controlled-substances/ecdd_41_meeting/en/.*

III. Substances Under WHO Review

ADB–FUBINACA (chemical name: *N*-[1-(aminocarbonyl)-2,2-dimethylpropyl]-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide) is an indazole-based synthetic cannabinoid that is a potent, full agonist at CB1 receptors. This substance functionally (biologically) mimics the effects of the structurally unrelated delta-9-tetrahydrocannabinol (THC), a Schedule I substance, and the main psychoactive chemical constituent in the cannabis (marijuana) plant. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. ADB–FUBINACA use has been associated with serious adverse events including death in the United States. There are no commercial or approved medical uses for ADB–FUBINACA. On April 10, 2017, ADB–FUBINACA was temporarily controlled as a Schedule I substance under the CSA.

FUB–AMB (other names: MMB–FUBINACA; AMB–FUBINACA; chemical name: methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate) is an indazole-based synthetic cannabinoid that is a potent full agonist at CB1 receptors. This substance functionally (biologically) mimics the effects of the structurally unrelated THC, a Schedule I substance, and the main psychoactive chemical constituent in marijuana. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. FUB–AMB use has been associated with serious adverse events including death in the United States. There are no commercial or approved medical uses for FUB–AMB. On November 3, 2017, FUB–AMB was temporarily controlled as a Schedule I substance under the CSA.

ADB–CHMINACA (other name: MAB–CHMINACA; chemical name: *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indole-3-carboxamide) is an indazole-based synthetic cannabinoid that is a potent full agonist at CB1 receptors. This substance functionally (biologically) mimics the effects of the structurally THC, a Schedule I substance, and the main psychoactive chemical constituent in marijuana. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. ADB–CHMINACA use has been associated with serious adverse events including death in the United States. There are no commercial or approved medical uses for ADB–CHMINACA. On February 5, 2016, ADB–CHMINACA was temporarily controlled as a Schedule I substance under the CSA.

CUMYL–4CN–BINACA (chemical name: 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1 H-indazole-3-carboxamide) is a clandestinely produced indazole-3-carboxamide based synthetic cannabinoid that has been sold online and used to mimic the biological effects of THC, the main psychoactive chemical constituent in marijuana. Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. Hospital, scientific publications and law enforcement reports show that CUMYL–4CN–BINACA is abused for its psychoactive properties. CUMYL–4CN–BINACA has been associated with serious adverse events in the United States, in addition to multiple deaths in Europe. CUMYL–4CN–BINACA has no commercial or medical uses. On July 10, 2018, CUMYL–4CN–BINACA was temporarily controlled as a Schedule I substance under the CSA.

Cyclopropyl fentanyl is a synthetic opioid that has a pharmacological profile similar to other Schedule I and II controlled opioid substances such as acetyl fentanyl, fentanyl, and other related mu-opioid receptor agonist substances. This clandestinely produced analog of fentanyl is associated with adverse events typically associated with opioid use such as respiratory depression, anxiety, constipation, tiredness, hallucinations, and withdrawal. Cyclopropyl fentanyl has been associated with numerous fatalities. At least 115 confirmed overdose deaths involving cyclopropyl fentanyl abuse have been reported in the United States. Cyclopropyl fentanyl has no commercial or currently accepted medical uses in the United States. On January 4, 2018, cyclopropyl fentanyl was temporarily placed into Schedule I of the CSA.

Methoxyacetyl fentanyl has a pharmacological profile similar to other Schedule I and II opioid substances such as acetyl fentanyl, fentanyl, and other related mu-opioid receptor agonist substances. Evidence suggests that the pattern of abuse of fentanyl analogues, including methoxyacetyl fentanyl is similar to heroin and prescription opioid analgesics. Law enforcement and public health reports demonstrate that methoxyacetyl fentanyl is being illicitly distributed and abused. The Drug Enforcement Administration (DEA) is aware of at least two overdose deaths associated with the abuse of methoxyacetyl fentanyl in the United

States. Methoxyacetyl fentanyl has no currently accepted medical use in treatment in the United States. On October 26, 2017, methoxyacetyl fentanyl was temporarily placed into Schedule I of the CSA.

Ortho-fluorofentanyl has a pharmacological profile similar to fentanyl and other related mu-opioid receptor agonist. *Ortho*-fluorofentanyl has no currently accepted medical use in treatment in the United States. *Ortho*-fluorofentanyl has been encountered by law enforcement and public health officials. The DEA has received reports for at least 13 confirmed overdose deaths involving *ortho*-fluorofentanyl abuse in the United States. On October 26, 2017, *ortho*-fluorofentanyl was temporarily placed into Schedule I of the CSA.

Para-fluorobutyrfentanyl shares pharmacological profile with other Schedule I (*e.g.,* butyryl fentanyl) and II (*e.g.,* fentanyl) opioid substances. *Para*-fluorobutyrfentanyl has no currently accepted medical use in treatment in the United States. The abuse of *para*-fluorobutyrfentanyl carries public health risks similar to that of heroin, fentanyl, and prescription opioid analgesics. On February 1, 2018, *para*-fluorobutyrfentanyl was temporarily placed into Schedule I of the CSA.

Para-methoxybutyrfentanyl shares pharmacological profile with other Schedule I (*e.g.,* butyryl fentanyl) and II (*e.g.,* fentanyl) opioid substances. *Para*-methoxybutyrfentanyl has no currently accepted medical use in treatment in the United States. The abuse of *para*-methoxybutyrfentanyl carries public health risks similar to that of heroin, fentanyl, and prescription opioid analgesics. On February 1, 2018, *para*-methoxybutyrfentanyl was temporarily placed into Schedule I of the CSA.

N-ethylnorpentylone (other name: *N*-ethylpentylone) is a synthetic cathinone with stimulant and psychoactive properties similar to cathinone, a Schedule I substance. *N*-ethylpentylone abuse has been associated with adverse health effects leading to emergency department admissions, and deaths. *N*-ethylpentylone has no currently accepted medical use in treatment in the United States. On August 31, 2018, *N*-ethylnorpentylone was temporarily controlled as a Schedule I substance under the CSA.

Tramadol, an opioid analgesic, was first approved by the FDA for medical use in March of 1995 for the treatment of moderate to moderately severe pain. It is available as immediate-release, extended-release, and combination products containing acetaminophen. Tramadol has been abused alone or in combination with other psychoactive substances. On July 2, 2014, the DEA issued a Final Rule controlling tramadol as a Schedule IV substance under the CSA with effective date of August 18, 2014.

The ECDD pre-reviewed tramadol at its 39th meeting in November 2017 noting growing evidence of abuse of tramadol in many countries, in some cases serious, accompanied by adverse reactions and tramadol-associated deaths and recommending that tramadol be subject to a critical review at a subsequent meeting.

Pregabalin is an FDA-approved medication in the United States and is available as an oral capsule and oral solution and approved for the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, and adjunctive therapy for partial onset seizures, fibromyalgia, and neuropathic pain associated with spinal cord injury. Although the mechanism of action of pregabalin is unknown, pregabalin is thought to produce its therapeutic effects on neuropathic pain via binding with high affinity to the alpha 2-delta receptor site (a subunit of voltage gated calcium channels) within the central nervous system. Reports indicate that patients are self-administering higher than recommended doses to achieve euphoria, especially patients who have a history of substance abuse, particularly opioids. While effects of excessively high doses are generally non-lethal, gabapentinoids such as pregabalin are increasingly being identified in postmortem toxicology analyses. Pregabalin is a Schedule V controlled substance in the United States under the CSA. At its 39th meeting in November 2017, the WHO Expert Committee on Drug Dependence (ECDD) pre-reviewed pregabalin and, noting increasing evidence of misuse and abuse in many countries, the ECDD recommended that pregabalin be subject to a future critical review.

Cannabis, also known as marijuana, is a plant known by biological names *Cannabis sativa* or *Cannabis indica.* It is a complex plant substance containing multiple cannabinoids and other compounds, including the psychoactive chemical THC and other structurally similar compounds. Cannabinoids are defined as having activity at cannabinoid 1 and 2 (CB1 and CB2 respectively) receptors. Agonists of CB1 receptors are widely abused and are known to modulate motor coordination, memory processing, pain, and inflammation, and have anxiolytic effects.

The principal cannabinoids in the cannabis plant include THC, cannabidiol (CBD), and cannabinol. These substances are controlled in Schedule I under the CSA. The synthetically derived single pure stereoisomer, (−)-trans-delta-9-THC (also known as dronabinol) is the active ingredient in two approved drug products in the United States, MARINOL (dronabinol) capsules (and generics) and SYNDROS (dronabinol) oral solution. MARINOL is controlled in Schedule III, while SYNDROS is controlled in Schedule II under the CSA. Both MARINOL and SYNDROS are approved to treat anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS), and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatment.

CBD is another cannabinoid constituent of the cannabis plant. In the United States, one CBD-containing product, Epidiolex oral solution, has received marketing approval by FDA for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients 2 years of age and older. The CBD in Epidiolex is extracted and purified from the cannabis plant. Currently, CBD is controlled generally as a Schedule I substance under the CSA. However, the recent scheduling action on September 28, 2018, by the DEA for Epidiolex, and any future, similar formulations of CBD that become FDA-approved medications, places these FDA-approved CBD formulations in Schedule V under the CSA.[1] CBD is not specifically listed in the schedules of the 1961, 1971, or 1988 International Drug Control conventions.

At the 40th (2018) meeting of the ECDD, the committee critically-reviewed CBD and pre-reviews of cannabis plant and resin; extracts and tinctures of cannabis; THC; and isomers of THC. The 40th ECDD recommended that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions, and that cannabis plant and resin; extracts and tinctures of cannabis; THC; and isomers of THC proceed to a Critical Review.

IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites

[1] *https://www.ecfr.gov/cgi-bin/text-idx?SID=f43ff6b6883b0b81774fab03dcea8fa5&mc=true&node=pt21.9.1308&rgn=div5#se21.9.1308_115.*

interested persons to submit comments regarding the 16 drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in mid-2018. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA.

Dated: October 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21954 Filed 10–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2016–D–1254]

Assessing Adhesion With Transdermal and Topical Delivery Systems for Abbreviated New Drug Applications; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' This revised draft guidance supersedes the draft guidance entitled ''Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs,'' which was announced in the **Federal Register** on June 1, 2016. This revised draft guidance provides recommendations for the design and conduct of studies evaluating the adhesive performance of a transdermal or a topical delivery system (collectively referred to as TDS). Depending on the objectives of a TDS product development program, applicants may choose to evaluate TDS adhesion in clinical studies performed to evaluate TDS adhesion only or in clinical studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and bioequivalence (BE) with pharmacokinetic (PK) endpoints). The recommendations in this revised draft guidance relate exclusively to studies submitted in support of an abbreviated new drug application (ANDA).

DATES: Submit either electronic or written comments on the revised draft guidance by December 10, 2018 to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *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 2016–D–1254 for ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' Received comments 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