§ 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Joint Commission's current term of approval for their hospital accreditation program expires July 15, 2020.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Joint Commission's request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether the Joint Commission's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospitals.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on December 18, 2019. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Joint Commission's standards for hospitals as compared with CMS' hospital CoPs.
- The Joint Commission's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of the Joint Commission's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ The Joint Commission's processes and procedures for monitoring a hospital found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the SA monitors corrections as specified at § 488.9.

++ The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ The Joint Commission's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of the Joint Commission's staff and other resources, and its financial viability.

++ The Joint Commission's capacity to adequately fund required surveys.

++ The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ The Joint Commission's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ The Joint Commission's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: February 6, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2020–03082 Filed 2–14–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0597]

Request for Information on Vaping Products Associated With Lung Injuries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is opening a docket to obtain data and information related to the use of vaping products that are associated with recent lung injuries. This request for information (RFI) responds to direction from Congress to gather information from the public that could help identify and evaluate additional steps the Agency could take to ''address the recent pulmonary illnesses reported to be associated with the use of e-cigarettes and vaping products.'' FDA is seeking information on product design and potential ways to prevent consumers from modifying or adding substances to these products that are not intended by the manufacturers. In particular, FDA is seeking data and information in the form of reports and manuscripts that are unpublished or not available through indexed bibliographic databases. FDA has searched the publicly available scientific literature and is now seeking to supplement that with information not included in the published scientific literature.

DATES: Submit either electronic or written comments or information by April 20, 2020.

ADDRESSES: You may submit either electronic or written comments 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–2020–N–0597 for ''Request for Information on Vaping Products Associated With Lung Injuries.'' 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.govinfo.gov/content/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: Samantha LohCollado, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov,* 1–877–287–1373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the opening of a docket entitled ''Request for Information on Vaping Products Associated With Lung Injuries.''

FDA remains deeply concerned about the recent lung injuries and deaths and is working closely with other agencies, as well as State and local public health partners, to investigate these incidents. To help gather and analyze as much information as possible, FDA is working closely with Federal and State partners to identify the vaping products or other substances that may be causing the injuries. Specifically, FDA is analyzing samples submitted by a number of States for the presence of a broad range of chemicals, including nicotine, tetrahydrocannabinol (THC) and other cannabinoids, along with cutting agents/diluents and other additives, pesticides, opioids, poisons, heavy metals, and toxins. As of February 3, 2020, FDA has received over 1,300 samples from 31 States and 1 territory with roughly 1,070 of these samples connected to patients.[1] These samples have been collected directly from consumers, hospitals, and State offices. They have included vaping devices and products containing varied levels of liquid as well as packaging and other documentation. FDA has not found one product or substance that is implicated in all of the cases; however, we do know that THC is present in most of the samples being tested and many of these samples have vitamin E acetate as a diluent. FDA is following all potential leads and is committed to taking appropriate actions as additional facts emerge.

On December 20, 2019, the President signed the ''Further Consolidated Appropriations Act, 2020'' which directs FDA to issue a RFI to solicit information regarding ''the recent pulmonary illnesses reported to be associated with the use of e-cigarettes and vaping products.'' [2] To further this goal, FDA is seeking information related to the use of vaping products that are associated with the recent lung injuries, including public comment on product design and ways to prevent the public from modifying or adding substances to these products that are not intended by the manufacturer. This information may be used by FDA to inform future rulemaking and review of industry premarket application submissions, or in taking other regulatory actions.

II. Request for Information

FDA seeks to obtain data and information related to the use of vaping products that are associated with recent lung injuries. FDA has searched the publicly available scientific literature and is now seeking to supplement that search with information from other sources, specifically unpublished data or other information. If the work is not directly conducted in tobacco products,

[1] For more information regarding FDA's current efforts to identify and address lung injuries related to the use of vaping products, please see *https://www.fda.gov/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products.*

[2] Further Consolidated Appropriations Act, 2020, Public Law 116–94, § 785. FDA uses the term ''vaping products'' for purposes of this RFI. ''Vaping products'' include e-cigarettes as well as other electronic nicotine delivery systems (ENDS). *See* ''Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization,'' available at *https://www.fda.gov/industry/fda-basics-industry/guidances* (defining ''ENDS'' as including ''include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. For example, FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes to be ENDS.'')

responses should include a discussion of how the information or data can be applied specifically to tobacco products or to lung injuries associated with the use of vaping products.

For this RFI, FDA is requesting: (1) Unpublished data or information (summarized); (2) unpublished or prepublication copies of manuscripts, conference presentations, and/or posters; (3) dissertations and/or theses; and (4) white papers or other unpublished reports. FDA is requesting data and information from all interested parties, including, but not limited to, academic and government researchers, industry, and any other sources.

Specifically, FDA is requesting unpublished data or information on the following:

- Specific chemicals, compounds, ingredients or combinations of ingredients that when inhaled or aerosolized, may be associated with the symptoms observed in ''e-cigarette, or vaping, product use-associated lung injury'' (EVALI) patients; *e.g.,* cough, chest pain, shortness of breath, abdominal pain, nausea, vomiting, diarrhea, fever, chills; [3]
- nature of pulmonary pathological changes associated with inhaling the specific chemicals, compounds, ingredients, or combinations of ingredients that elicit the symptoms observed in EVALI;
- methods or sources for obtaining chemicals, compounds, ingredients, or combinations of ingredients, other than those intended by the manufacturer, that are added to vaping products;
- in what ways and how frequently consumers add chemicals, compounds, ingredients or combinations of ingredients, other than those intended by the manufacturer, to vaping products and how these changes affect the health impacts, frequency, and patterns of consumer use of the products;
- methods for identifying and detecting materials added or modifications to vaping products after the manufacturing process and not intended by the manufacturer; and
- methods of changing the manufacturing process or product design features for vaping products that will reduce or prevent consumers from modifying products after the manufacturing process.

Data may come from studies outside of the United States; however, FDA prefers that reports be submitted in English.

[3] For more information concerning the symptoms observed in EVALI patients, please see *https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/need-to-know/index.html#symptoms.*

When submitting information, please include details about how the data were collected, including the sample composition, year(s) of data collection, and a detailed summary of the methods and measures used. For data summaries, please include both point estimates and measures of variance, as well as effect sizes (if available).

Please also note that when submitting information and data to the docket, certain compressed file formats (*e.g.,* zip files) are not allowed. Acceptable file formats include: .doc, .docx, .pdf, .ppt, .pptx, .rtf, .txt, .xls, .xlsx, .xlsm, .xlsb, and .wpd.

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03160 Filed 2–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0259]

Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Patient-Focused Drug Development for Stimulant Use Disorder.'' The purpose of the public meeting is to allow FDA to obtain stakeholder perspectives on the impact of stimulant use disorder and views on treatment approaches for stimulant use disorder.

DATES: The public meeting will be held on March 10, 2020, from 12:30 p.m. to 5 p.m. Submit either electronic or written comments on this public meeting by May 11, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Silver Spring Civic Building, 1 Veterans Pl., Silver Spring, MD 20910. The building is located at Veterans Plaza in downtown Silver Spring and is accessible via the Silver Spring Metro Station on the Red Line. Paid public parking is also available at the Town Square Garage (Garage 61), 801 Ellsworth Dr., Silver Spring, MD 20910, and the Wayne-Ellsworth Garage (Garage 60), 921 Wayne Ave., Silver Spring, MD 20910. For more information regarding parking, Metro access, and the meeting location, please refer to *https://www.montgomerycountymd.gov/cupf/info-reservation/SSCB.html.*

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 May 11, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 11, 2020. 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.''