4164-01-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 In particular, FDA is seeking data and information in the form of reports and manuscripts that are unpublished or not available through indexed bibliographic databases.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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

[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.

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, 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.

[2] Further Consolidated Appropriations Act, 2020, Pub. L. 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.")

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;

[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.

- 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.

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.

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