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July 6, 2022

Virginia Commonwealth  
University  
Office of the Vice President for  
Research and Innovation

MEMORANDUM FOR DISTRIBUTION

Human Research Protection  
Program

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FROM: HUMAN RESEARCH PROTECTION PROGRAM

SUBJECT: FDA DENIES AUTHORIZATION TO MARKET  
JUUL PRODUCTS

P. Srirama Rao, PhD  
Institutional Official  
Vice President for Research and  
Innovation

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Human Research Protections Program  
Director

1. DISCUSSION: On Thursday, June 23, 2022, the U.S. Food and Drug Administration (FDA) issued marketing denial orders (MDOs) to Juul Labs, Inc. for all of their products currently marketed in the United States. As a result, the company must stop selling and distributing these products.

A U.S. federal appeals court on Friday, June 24, 2022, put on hold the FDA's ban on sales of Juul Labs, Inc's e-cigarettes after the company appealed the health agency's order and said the ban would cause it "irreparable harm." The U.S. Court of Appeals for the District of Columbia Circuit said the purpose of the stay was to allow the court sufficient time to consider Juul's briefing for an emergency review and not a ruling on the merits of that motion.

On July 5, 2022, FDA administratively stayed the marketing denial order. The agency has determined that there are scientific issues unique to the Juul application that warrant additional review. **This administrative stay temporarily suspends the marketing denial order during the additional review but does not rescind it.** All electronic nicotine delivery systems, or ENDS products, including those made by Juul, are required by law to have FDA authorization to



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be legally marketed. **The stay and the agency's review do not constitute authorization to market, sell, or ship Juul products.**

2. FACTORS BEARING THE PROBLEM:

- a. Juul Labs, Inc filed an emergency injunction in federal court to **hold** the ban issued by the FDA.
- b. The key factor to this problem is that the FDA has not issued formal written guidance related to the ban on Juul Labs, Inc.

3. PROBLEM: There are several active and pending studies conducted at Virginia Commonwealth University that have incorporated the use of Juul products (including Juul devices and/or Juul pods) in the research methodology. Thus, how will the ban issue by the FDA impact active and pending human subject research at VCU?

4. CONCLUSION: Due to the lack of formal guidance by the FDA at this time, the Human Research Protection Program at VCU developed the following course of action to aid principal investigators to navigate the new regulatory conundrum.

5. ACTION REQUIRED:

- a. For Human Subject Research protocol(s) with active participants that have **acquired** Juul products (including Juul devices and/or Juul pods) prior to June 23, 2022, you must complete the following course of action:
  - i. Submit the respective research protocol to the FDA for review as a request to use an **investigational tobacco product (ITP)**.
    1. The three ways an investigator can submit to CTP in the FDA:
      - a. Paper format mailed in
      - b. Electronic format (CD/DVD) mailed in
      - c. Or electronic via CTP portal (FDA recommended for efficiency) <https://ctportal.fda.gov/ctportal/login.jsp>
    - ii. Submit an amendment to the protocol with the Institutional Review Board of Record indicating the following elements:
      1. ITP was submitted to the FDA for review.
      2. Revisions to the informed consent form address the recent development from the FDA.



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3. Upload a copy of the protocol that was submitted to the FDA in the ITP application.
      4. Annotate the revisions to the protocol, informed consent form, and submission to the FDA in the RAMS IRB Smartform.
    - iii. These studies should not proceed with using Juul products (including Juul devices and/or Juul pods) until an amendment (as noted in 5.a.ii. above) has been submitted to, and approved by, the IRB of record and an ITP application submitted to the FDA.
    - iv. Contact your respective program officer for additional information regarding this issue (if applicable).
  - b. For currently approved Human Subject Research Protocol(s) that have not acquired Juul products (including Juul devices and/or Juul pods) prior to June 23, 2022, you will not be allowed to continue with the currently approved protocol to acquire Juul products. Thus, the principal investigator will have to complete the following course of action:
    - i. Submit an amendment to the protocol with the Institutional Review Board of Record indicating the following elements:
      1. Removal of the use of Juul products (including Juul devices and/or Juul pods) from the protocol.
      2. Modify the protocol to address the removal of Juul products (including Juul devices and/or Juul pods) and/or research methodology and subject visit schedule.
      3. Revisions to the informed consent form address the recent development from the FDA.
      4. Annotate the revisions to the protocol, and informed consent form in the RAMS IRB Smartform.
    - ii. Contact your respective program officer for additional information regarding this issue (if applicable).
  - c. For Pending Human Subject Research Protocol(s) that have not acquired Juul products (including Juul devices and/or Juul pods) prior to June 23, 2022, you must complete the following course of action:
    - i. Modify the protocol to remove the use of Juul products (including Juul devices and/or Juul pods) from the protocol.
      1. Modify the protocol to address the removal of Juul products (including Juul devices and/or Juul pods) and/or research methodology and subject visit schedule.



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2. Revisions to the informed consent form address the recent development from the FDA.
  3. Annotate the revisions to the protocol, and informed consent form in the RAMS IRB Smartform.
- ii. Once the modifications are made, the Principal Investigator may submit the protocol to the IRB of Record for review.
  - iii. Contact your respective program officer for additional information regarding this issue (if applicable).

If you have any questions or concerns, please contact the VCU IRB Office at [irbpanela@vcu.edu](mailto:irbpanela@vcu.edu).

Respectfully,

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Director, Human Research Protections Program

Office of the Vice President for Research and Innovation

Virginia Commonwealth University



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