

## Investigational Tobacco Products Guidance

NIH-funded investigators who are designing a protocol involving administration of a tobacco product to humans should discuss the protocol with the Food and Drug Administration (FDA) Center for Tobacco Products (CTP), as described here. These recommendations are subject to change should the FDA compliance policy change.

1. There is no need to contact the FDA CTP if the protocol involves administration of tobacco products that meet the following criteria:
  - a. The investigator has established that the products were on the market prior to August 8, 2016.\*
  - b. The products will not be modified in any way for use in the investigation.
2. If the investigator is unable to establish whether the tobacco product was on the market prior to August 8, 2016,\* the investigator should reach out to the FDA CTP at: [CTP-OS-ITP@fda.hhs.gov](mailto:CTP-OS-ITP@fda.hhs.gov).

The email should:

- a. Clearly and uniquely identify the product(s) by brand and sub-brand—including the type or category of tobacco product (e.g., cigarette, smokeless tobacco, cigar, electronic nicotine delivery systems [ENDS], waterpipe tobacco) and subcategory (e.g., closed or open e-cigarette, closed or open e-liquid). Provide as much information as possible as this will facilitate FDA CTP efforts to evaluate the marketing status.
- b. When possible, include additional identifiers (e.g., stock-keeping units [SKUs], Universal product codes [UPCs], catalog numbers).
- c. Provide additional available information such as packaging type, package quantity, and/or characterizing flavor.

The FDA CTP will determine if they have information regarding the marketing status of the product(s) prior to August 8, 2016.\*

3. Once the FDA CTP receives the email, they will make every effort to respond via email within 2 weeks.
  - a. If the FDA CTP **can** determine the tobacco products were marketed prior to August 8, 2016\* and the investigator does not intend to modify the products, the FDA CTP will indicate no additional review is needed. The NIH will consider the FDA CTP's email response as sufficient documentation.
  - b. If the FDA CTP is **not** able to determine the tobacco products were marketed prior to August 8, 2016,\* the FDA CTP will indicate this. The investigator should then submit their protocol for review in an investigational tobacco products (ITP) request, as per the revised FDA Draft Guidance for [Use of Investigational Tobacco Products](#).

Note that the FDA CTP intends to respond to investigators within 60 days of receipt of protocols for review. Investigators should receive acknowledgement of the submission with the name and contact information for the assigned Regulatory Health Project Manager (RHPM). If investigators do not receive a response within 60 days, they should contact the RHPM. Investigators may also contact their NIH Program Officer to discuss additional steps/actions.

4. If the marketed products (regardless of the date they entered the market) will be used with investigator-manipulated modification(s), then the investigator should submit an ITP request. In addition to the protocol and other information described in the FDA Draft Guidance, the ITP request should also include:
  - a. A description of the planned modification(s).
  - b. A rationale for how these modification(s) support the study design and do not increase risk to human participants.

\*This date applies to all tobacco products regulated by the FDA under the 2009 Family Smoking Prevention and Tobacco Control Act (<https://www.fda.gov/tobacco-products/products-guidance-regulations>), including tobacco products added via the “Deeming Rule.”