



January 22, 2015

VIA Electronic Mail

Dear Registrant,

You are receiving this letter because you are listed as your firm's point of contact for establishment registration and product listing submissions. The Center for Tobacco Products (CTP) is providing this notice to tobacco product registrants that it intends to create and make public, two separate searchable databases containing establishment registration and product listing information beginning in April 2015. Being a current registrant, CTP wants to ensure that you are fully aware of the content and manner in which this information will be made available through the Food and Drug Administration's (FDA) website.

Section 905(f) of the Federal Food Drug and Cosmetic Act (FD&C Act) (21 U.S.C. § 387e(f)) specifically mandates that registration information be made "available for inspection, to any person so requesting." CTP is creating searchable databases as part of its effort to implement this statutory obligation. The content of these separate databases will not be linked, meaning that product listings will not be linked with establishment information. The databases will only include the same type of information that has previously been made available in response to Freedom of Information Act requests.

Section 905 of the FD&C Act (21 U.S.C. § 387e) provides that certain information must be included when registering your establishment. This registration information includes the name and places of business of every owner or operator of a domestic establishment manufacturing, preparing, compounding, or processing tobacco products. The searchable establishment information made available by CTP will include the following fields:

- Establishment Name
- Establishment State
- Establishment Country
- Establishment Operation(s)
- Establishment FEI
- Owner or Operator Name
- Owner or Operator FEI

Section 905(i)(1) of the FD&C Act (21 U.S.C. § 387e(i)(1)) requires that every person who registers must "at the time of registration" file a list of all tobacco products being manufactured, prepared, compounded, or processed by that person for commercial distribution. Searchable product information will include the following fields:

- Product Name
- Product Category (i.e. cigarettes, smokeless, RYO, or cigarette tobacco)

If you have any questions or concerns about the content of this message, please direct them to [CTPRegistrationandListing@fda.hhs.gov](mailto:CTPRegistrationandListing@fda.hhs.gov). Our office will be glad to provide any support you may need. Thank you.

Sincerely,

/s/

Joanna Weitershausen

Director

Division of Enforcement and Manufacturing

Office of Compliance and Enforcement

Center for Tobacco Products