

Revised Guidances Address Meetings With FDA, Registration and Product Listing

Two guidance documents, “Meetings with Industry and Investigators on the Research and Development of Tobacco Products,” and “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments,” have been updated to represent FDA’s current thinking on the topics covered.

“Meetings with Industry and Investigators on the Research and Development of Tobacco Products”

This revised guidance for industry and investigators describes FDA’s current policies and recommendations with respect to agency meetings with tobacco manufacturers, importers, researchers, and investigators. In particular, the guidance is about meetings with the agency relating to plans to conduct research to inform the regulation of tobacco products or support the development or marketing of tobacco products. The guidance is intended to help those seeking a meeting with FDA to discuss their research and development plans, and it includes information about how to request a meeting, what to include in a meeting request, and what information to submit prior to the meeting.

The complete guidance is available by visiting FDA’s [website](#).

“Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments”

This guidance document has been revised to reflect changes in FDA authorities over “deemed” tobacco products and is intended to assist owners and operators of domestic tobacco product establishments with the registration and product listing submissions required by section 905 of the Food, Drug, and Cosmetic Act (FD&C Act). The document explains, among other things, the requirement to make establishment registration and product listing submissions; who should make establishment registration and product listing submissions; what information to include in the submissions; how and when to submit the information; and FDA’s compliance policies.

The full guidance can be found on FDA’s [website](#).