Fact Sheet

Advocacy Comments on FDA's Proposed Rule on Tobacco Product Manufacturing Practice Requirements

On March 10, 2023, the Food and Drug Administration (FDA) published a proposed rule that would establish tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products. FDA's expansive tobacco product manufacturing practice proposal would provide an "umbrella" procedural framework related to the manufacture, preproduction design validation, packing, and storage of all types of tobacco and deemed tobacco products. On September 27, 2023, the Office of Advocacy (Advocacy) filed a comment letter recommending FDA publish a supplemental initial regulatory flexibility analysis (IRFA).

Advocacy advised that:

- FDA must adequately describe the regulated small entities and estimate potential impacts to those entities in a supplemental IRFA.
- FDA should use detailed information to analyze the relative impact of the costs of the proposed rules to small entities based on their size.
- FDA should analyze costs borne by industry segments where the regulation would require novel or complex compliance measures.
- FDA's supplemental IRFA must include a description of significant alternatives to the proposed rules which accomplish its objectives for the rulemaking.
- FDA should provide a detailed analysis of each significant alternative and discuss how it may reduce the economic burden on small entities.

A complete copy of Advocacy's letter to FDA is available at: Advocacy's Letter to FDA. For more information please contact Meagan Singer, Assistant Chief Counsel at meagan.singer@sba.gov or (202) 921-4843.