

Module 1.10 Health Document [904(a)(4)] and Requested Documents [904(b)]

1. HEALTH DOCUMENTS [904(a)(4)]

All documents required by section 904(a)(4) of the FD&C Act, 21 U.S.C. 387d(a)(4), and current FDA policy are included within the corresponding PMTAs. Accordingly, we believe these submissions comply with the requirement in section 904(a)(4) of the FD&C Act to submit tobacco health documents 90 days in advance of a tobacco product's introduction into interstate commerce and that no other submission is required for the new products. If FDA requires a separate (and duplicative) submission of tobacco health documents, we will make such a submission at the Agency's request. We will reference these initial submissions in a future submission to FDA regarding the other requirements imposed by section 904(a)(4) of the FD&C Act [21 U.S.C. 387d(4)].

2. HEALTH DOCUMENTS [904(b)]

We will comply with any legally valid data submission request made by the FDA under section 904(b) of the FD&C Act [21 U.S.C §387d(b)].