



Change Request for OMB Control No. 0910-0654

Tobacco Health Document Submission

March 2023

The Food and Drug Administration (FDA, us, or we) is submitting this nonmaterial/non-substantive change request (83-C) to include a revised version of the associated Tobacco Health Document submission guidance.

Per the conforming changes from the Consolidated Appropriations Act of 2022 we are revising this guidance to amend the term "tobacco product" in the FD&C Act to include products that contain nicotine from any source. In the previous ICR under this control number (Reference # 202201-0910-006), we noted that the scope of the collection was expanding to cover the submission by these products, but the guidance would be included later. No other changes are being made to the information collection.

Tracked guidance:



Health Docume
Guidance (tracked)