



Change Request for OMB Control No. 0910-0775

Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

August 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 guidance.

Per the conforming changes from 21 CFR 1100.202, we are revising this guidance to replace the term “grandfathered” with “pre-existing” / “pre-existing tobacco product”. FDA has changed the term “grandfathered tobacco product” to “pre-existing tobacco product” because it more appropriately describes these products. Specifically, FDA considers a “pre-existing tobacco product” to mean a tobacco product that was commercially marketed in the United States as of February 15, 2007. No other changes are being made to the information collection.

Tracked guidance:



Establishing a
Tobacco Was Comm