



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1996-D-0405]

Compliance Policy Guide Sec. 110.100; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of Compliance Policy Guide Sec. 110.100, “Certification for Exports” (CPG Sec. 110.100), which FDA issued in 1980. We are taking this action because CPG Sec. 110.100 contains information that is either duplicative of other information we have published or no longer reflects the Agency’s current thinking.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Tiffany Kelley, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-348-1970, Tiffany.Kelley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA originally issued CPG Sec. 110.100 on October 1, 1980, in the Agency’s Manual of Compliance Policy Guides. The CPG was revised periodically but has not been revised since April 14, 2000.

Since FDA last revised CPG Sec. 110.100, the Agency issued separate guidance for industry on FDA export certification in 2004. FDA revised that guidance in 2005, 2019, and, most recently, in August 2021. The August 2021 version of the guidance for industry, entitled “FDA Export Certification,” provides the Agency’s current guidance regarding FDA issuance of export certification. Persons with access to the internet may obtain the guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Although this

guidance originally complemented the content in CPG Sec. 110.100, changes in the document over time have increasingly resulted in CPG Sec. 110.100 containing duplicative and outdated information. Thus, FDA is withdrawing CPG Sec. 110.100 in its entirety.

Dated: November 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-24234 Filed: 11/4/2021 8:45 am; Publication Date: 11/5/2021]