# Compliance Policy Guide Section 110.800
# Post Detention Sampling
# Guidance for Industry

**This guidance is for immediate implementation.**

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit one set of either electronic or written comments on this guidance at anytime. Submit electronic comments to https://www.regulations.gov/. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with docket number FDA-2019-N-0999.

For questions regarding this draft document contact the ORA Office of Strategic Planning and Operational Policy (OSPOP) at ORAPolicyStaffs@fda.hhs.gov.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Office of Regulatory Affairs**

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## I. INTRODUCTION

This Compliance Policy Guide (CPG) provides guidance to importers whose U.S. Food and Drug Administration (FDA) regulated articles offered for import have been detained by U.S Customs and Border Protection (CBP). A previous version of this CPG, numbered 110.800, was revised in FDA's Compliance Policy Guides Manual in 1989. This CPG supersedes that version and includes minor revisions to clarify existing language, as well as other minor stylistic revisions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

## II. BACKGROUND

Importers of articles regulated by the FDA sometimes request permission from the FDA for samples to be collected from an article they have offered for import but that has been detained by CBP on behalf of FDA. The article may be in the physical possession of the importer and held under redelivery bond, or the article may be in the custody of CBP pending final disposition.

## III. POLICY

The FDA does not object to the collection of reasonable samples from a detained article for appropriate analysis or other appropriate examination, such as for the purpose of introducing evidence relevant to the admissibility, destruction, or reconditioning of the article, or to explore the possibility of reconditioning the article. Regardless of whether the article is in CBP custody or in the physical possession of the importer under redelivery bond, the importer is responsible for obtaining permission from CBP for the sample collection and complying with any CBP

requirements. The importer should take the steps necessary to account to CBP for whatever amount is missing from the article due to the sampling if he or she is called upon to redeliver the detained article to CBP custody for destruction or exportation.

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## IV. REFERENCES


1. U.S. Food and Drug Administration. Manual of Compliance Policy Guides. Last updated 09/19/2018. Last accessed 3/12/2020. https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm