

Compliance Policy Guide CPG Sec. 110.650 Weekly Entry Filing Guidance for Industry and FDA Staff

This guidance is for immediate implementation.

The FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2019-D-3904.

**U.S. Department of Health and Human Services
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Compliance Policy Guide

CPG Sec. 110.650

Weekly Entry Filing:

Guidance for Industry and FDA Staff¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

Introduction

The purpose of this Compliance Policy Guide (CPG) is to provide guidance to FDA staff and trade regarding requests to the FDA, for a preliminary admissibility assessment of FDA-regulated products that would be included in a weekly entry filing (WEF). The FDA recommends that persons who wish to file a weekly entry with the U.S. Customs and Border Protection (CBP) under 19 CFR 146.63(c)(1), request a preliminary admissibility assessment from the FDA before filing a request for a weekly entry with the CBP. The preliminary admissibility assessments are for the purpose of FDA reviewing whether the product is a good candidate for WEF, based on compliance with FDA-administered regulatory requirements and other factors relevant to FDA's admissibility review. This CPG describes what information the FDA needs to make a preliminary admissibility assessment.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, a guidance describes our 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 guidance means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Office of Strategic Planning and Operational Policy and the Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration.

Background

Foreign-Trade Zones (FTZ) are established under the Foreign Trade Zones Act and the general regulations and rules of procedure of the Foreign Trade Zones Board contained in 15 CFR part 400. Part 146 of 19 CFR governs the admission of merchandise into an FTZ; manipulation, manufacture, or exhibition in a zone; exportation of the merchandise from a zone; and transfer of merchandise from a zone into Customs territory. FTZs are secure areas under CBP supervision and are generally located in or adjacent to CBP ports of entry.

The FTZ program was designed to promote American competitiveness by encouraging companies to maintain and expand their operations in the United States. The FTZ program encourages U.S.-based operations by removing certain disincentives associated with manufacturing in the United States.

Weekly entry filing (WEF) is a program implemented by CBP that allows merchandise withdrawn from FTZs to be the subject of a single estimated weekly entry filed on or before the first day of the seven-day period in which the merchandise is to be withdrawn. In practice, this allows the person making entry to file one weekly entry estimating the number of units of each type of merchandise anticipated to be transferred (or withdrawn) from an FTZ and then remove that merchandise from the FTZ during the seven-day period rather than having to file an entry each time products are removed from an FTZ. This estimated weekly entry of multiple units (and sometimes multiple entry lines²) is treated as a single entry and single release of merchandise. If CBP does not accept a weekly entry, withdrawal of an article from an FTZ will be processed the same as other entries. This means that those entries will require submission of an entry each time merchandise from the FTZ is removed at the time of actual withdrawal.

While CBP is ultimately responsible for accepting or rejecting a WEF, FDA may also review WEF requests to help facilitate CBP's determination. FDA does this by providing a preliminary admissibility assessment on the FDA-regulated products. For products that have received a positive FDA preliminary assessment FDA will adjust its import screening system to allow for automated processing of future FTZ withdrawal entries. This may allow for entries participating in WEF to be given a system "May Proceed." Because WEF products are given this system "May Proceed," the products are not typically redelivered to FDA for sampling or examination. Consequently, the purpose of FDA's review is to ensure that the products that are approved for WEF are unlikely to pose safety concerns such that FDA would request to sample or examine the products or refuse entry. In order to conduct FDA's review, FDA asks for certain information from entry filers.

FDA-regulated products that are entered via a weekly entry filing remain subject to Section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381), and FDA may determine in some cases that it is appropriate to examine such products and/or refuse admission.

² In the WEF context, a unit refers to an individual piece of merchandise or FDA product that is removed as part of a weekly entry. Entries containing multiple products should be split into different lines wherever a data element is different from product to product. A weekly entry could contain various entry lines. Find more information on the entry process at <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/entry-process>.

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For example, if CBP accepts a WEF but the product appears violative at the time of entry, FDA

Discussion

FDA may provide an automated system “May Proceed” for FDA-regulated articles in a WEF accepted by CBP if the FDA has conducted a preliminary admissibility assessment that shows:

- 1) the articles in the WEF present a low public health risk, in that FDA is unlikely to have safety concerns that would cause the agency to sample or examine the product or refuse entry;
- 2) the articles in the WEF appear to meet the statutory and regulatory admissibility requirements that apply to the product at the time of FDA’s admissibility review of the entry;
- 3) the FDA is not aware of any information suggesting that the articles in the WEF or the firm have a history of violations of FDA requirements; and
- 4) all articles in the WEF are withdrawn for consumption from a single Foreign Trade Zone.

The following guidance explains what information should be provided to the FDA to enable the Agency to make a preliminary admissibility assessment of the FDA-regulated products that would be included in a WEF and the factors FDA will consider in making that preliminary assessment.

A. Information Needed for Preliminary Admissibility Assessment by the FDA

In order for the Agency to make a preliminary admissibility assessment of FDA-regulated products, the following information should be provided to the FDA:

- 1) CBP FTZ Information:
 - a. FTZ site and subzone information;
 - b. Port Information:
 - i. Port of Entry Name
 - ii. Port Code.
- 2) General Information for all Commodities:

Firm Information:

 - a. Name, address, and (if known) the FDA Facility Establishment Identifier (FEI), for the following firms related to product withdrawn from the FTZ;
 - i. Manufacturer:
 1. For products manufactured in an FTZ, the manufacturer within the FTZ from which the product is withdrawn;
 2. For products stored in an FTZ and subsequently entered into the United States, the site-specific foreign manufacturer of the product stored in the FTZ.
 - ii. Foreign Shipper:

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1. For products stored in an FTZ, the firm that ships the finished product from the foreign country into the FTZ;
2. For products manufactured in an FTZ, the foreign shipper is not needed for the submission of a WEF request.
 - b. Name, address, and (if known) the FDA FEI, of the IOR;
 - c. Firm FDA Registration number, as applicable.

Product information:

- a. Commercial product name;
 - b. Product description;
 - c. FDA product code of articles being withdrawn from the FTZ.
- 3) Evidence of compliance with the admissibility requirements that apply to the product. For information about which admissibility requirements may apply to the FDA-regulated product that would be included in your weekly entry filing with CBP, refer to the discussion of commodity specific information on the FDA's WEF webpage at <https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing>

Persons who are submitting a request to the FDA for a preliminary admissibility assessment of FDA-regulated products may use the spreadsheet available on the FDA FTZ/WEF website at <https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing>. The FDA FTZ/WEF website also has information on where to send the request.

A. Amenability of Product to Preliminary Admissibility Assessment by FDA

Some products and product types are generally not likely to be successful candidates for a preliminary admissibility assessment because the FDA has determined that they are usually not low-risk for purposes of WEF --- meaning that FDA may have safety concerns that may cause the Agency to want to conduct sampling or examination on the products offered for import. We do not recommend requesting WEF for such products. For other products, Centers consider some product categories to be generally low-risk for purposes of WEF, and thus amenable to WEF. To view a current list of products for which a Center determination of WEF amenability has been made, refer to the table for commodity specific information under "What information is submitted in my request to participate in WEF processing?" on FDA's WEF webpage at <https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing>

B. Product History

The FDA reviews the FDA compliance history for the manufacturer(s) and/or articles(s) associated with the WEF preliminary assessment request. Generally, the FDA is more likely to issue a positive preliminary admissibility assessment if there is a sufficient product history of consecutive shipments that have not been refused or released with comment. If the manufacturer has never offered products for importation into the U.S., FDA may conclude that there is not a basis for a positive preliminary admissibility assessment because we do not have enough

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information about whether future shipments are likely to be compliant with FDA requirements. Whether we issue a positive preliminary admissibility assessment may depend on other information available to the agency. If the manufacturer or shipper has a non-compliant history for specific imported products (e.g., imported products that have been previously refused or released with comment) FDA may be less likely to issue a positive preliminary admissibility assessment.

C. Firm History

FDA may consider the compliance history of the manufacturer(s) of the articles and the IOR associated with the WEF preliminary assessment request. The FDA is more likely to issue a positive preliminary admissibility assessment if the most recent inspection was classified by FDA as “No Action Indicated (NAI).” If the FDA has never inspected the manufacturer or IOR, the FDA could still issue a positive preliminary admissibility assessment depending on other available information. However, if the manufacturer or IOR has been inspected by the FDA and the most recent inspection was classified by the FDA as “Official Action Indicated (OAI)” or “Voluntary Action Indicated (VAI),” FDA may be less likely to issue a positive preliminary admissibility assessment.

D. Weekly Entries where FDA Preliminary Admissibility Assessment was not requested

Although the FDA recommends that persons who wish to file a weekly entry containing FDA-regulated products request a preliminary admissibility assessment from the FDA before filing a request for a weekly entry with CBP under 19 CFR 146.63(c)(1), there may be instances when a preliminary assessment has not been requested. FDA entry reviewers and field investigators should consider the status of the entry when determining how to proceed in making an admissibility decision. If the FDA reviews an entry that is later found to be part of a weekly entry filing approved by CBP that has not undergone an FDA preliminary admissibility assessment, the FDA may request CBP to order redelivery of the articles, particularly if FDA has safety concerns.

Paperwork Reduction Act of 1995

This guidance contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

This guidance refers to previously approved collections of information found in FDA regulations. The collections of information have been approved under OMB Control No. 0910-0046.

References

1. FDA Foreign Trade Zones/Weekly Entry Filing, available at <https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing>

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Last updated 11/30/2018.

2. FDA CPG 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers, available at

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-110600-fda-authority-over-products-foreign-origin-located-foreign-trade-zones-bonded>

Last updated 8/31/1989.