

From: FDA Office of Health and Constituent Affairs
<fdaofficeofhealthandconstituentaffairs@fda.hhs.gov>

Date: Monday, November 27, 2017 at 1:58 PM

Subject: Draft Guidance: Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.

Dear Colleague,

Today, FDA issued draft guidance for industry entitled, [Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier](#). This guidance describes how products without product identifiers will be exempted, as grandfathered, from certain requirements of section 582 of the Federal Food, Drug, and Cosmetic Act when the requirements become effective.

As explained in the draft guidance, a product without a product identifier would be grandfathered if there is accompanying documentation that it was packaged by a manufacturer before November 27, 2018.

The guidance provides our current thinking on how trading partners should treat grandfathered product for various activities. **Most significantly, as described in the draft guidance, trading partners may engage in transactions involving grandfathered products until the product expires, regardless of when the transaction occurs within the supply chain.** We also are reminding trading partners to be vigilant to protect patients from illegitimate drug products.

We invite your [comments](#) on the guidance.

Sincerely,
Shannon Thor, PharmD, MS

Lieutenant, US Public Health Service

Health Programs Coordinator

**Office of Health & Constituent Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301.796.8645
Shannon.Thor@fda.hhs.gov**

EXERPTS: INTERPRETATION OF SECTION 582(a)(5)(A) OF THE DSCSA

For the purposes of this guidance, a package or homogenous case of product is “in the pharmaceutical distribution supply chain” if it was packaged by the product’s manufacturer before November 27, 2018.

Consequently, a package or homogenous case of product that is not labeled with a product identifier is eligible for an exemption under section 582(a)(5)(A) as described in this guidance only **if the product's manufacturer packaged the product before November 27, 2018.**

Also, FDA made significant clarity for trading partners (wholesalers and dispensers) - **"trading partners may engage in transactions involving grandfathered products until the product expires, regardless of when the transaction occurs within the supply chain."**, thus also relieving questions about saleable returns in 2019.