California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item XI - Executive Officer's Report

---

a. Discussion and Consideration of FDA Draft Guidance, "Product Identifier Requirements under the Drug Supply Chain Security Act -- Compliance Policy"

Attachment 1

In late June, the FDA released a draft guidance document titled: "Product Identifier Requirements under the Drug Supply Chain Security Act -- Compliance Policy." The Drug Supply Chain Security Act establishes product tracing, product identifier, and verification requirements manufacturers, repackagers, wholesale distributors, and dispensers to enable the tracing of a product through the pharmaceutical distribution supply chain. The goal is to identify

In this guidance document, the FDA proposes to extend the compliance deadline from November 27, 2017, until November 28, 2018, by which manufacturers must comply with requirements to attach product identifiers under requirements of the Drug Supply Chain Security Act to individual products to cases of homogeneous products. The use of these identifiers will make it possible to do checking to identify counterfeit or suspect products in the supply chain.

A copy of the proposed guidance is provided in **Attachment 1.** Comments on this proposed guidance are due towards the end August.

The FDA states that it is proposing to move the compliance date back one year to ensure members of the supply chain will be able to comply with the requirements enacted in 2013. These entities have indicated that they could not be compliant with the November 2017 deadline. However, the FDA does state that "If a product has a product identifier, FDA expects manufacturers and downstream trading partners to use it in verification." The FDA will not be changing the deadline requirement that repackagers must create and imprint their repackaged products with a product identifier by November 28, 2018.

b. Update on CURES

Attachment 2

During this portion of the board meeting, staff from the California Department of Justice will provide a presentation on CURES 2.0. Tina Farales is expected to provide this presentation. **Attachment 2** provides an overview of CURES registration and use over the last three months.

Attachment 1

Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments 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 the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Office of Compliance at 301-796-3130 or drugtrackandtrace@fda.hhs.gov; or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

June 2017
Procedural

Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
and/or
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

June 2017
Procedural

TABLE OF CONTENTS

Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) 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.

I. INTRODUCTION

This draft guidance describes FDA's intention with regard to the enforcement of certain requirements related to product identifiers under the Drug Supply Chain Security Act. Specifically, this draft guidance addresses the requirement in section 582(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(b)(2)) that manufacturers "affix or imprint a product identifier[2] to each package[3] and homogenous case[4] of a product[5] intended to be introduced in a transaction[6] into commerce" beginning not later than November 27, 2017.[7] A drug product is misbranded if it fails to bear the product identifier as required by section 582 of the FD&C Act.[8] This draft guidance also addresses the requirements in section 582(b)(4) of the FD&C Act that, beginning November 27, 2017, manufacturers must: (1) use the standard numerical identifier, which is part of the product identifier, to verify product at the package level, when investigating suspect product or upon receiving a verification request from FDA;[9] (2) verify the product identifier of product in the possession or control of an authorized repackager, wholesale distributor, or dispenser who believes that such product was manufactured

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] *Product identifier* is defined in section 581(14) of the FD&C Act (21 U.S.C. 360eee(14)) as a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

[3] *Package* is defined in section 581(11) of the FD&C Act.

[4] *Homogeneous case* is defined in section 581(7) of the FD&C Act. The terms "homogeneous" and "homogenous" are used interchangeably throughout the DSCSA. FDA has chosen to use only the term "homogenous" throughout this guidance.

[5] *Product* is defined in section 581(13) of the FD&C Act.

[6] *Transaction* is defined in section 581(24) of the FD&C Act.

[7] See section 582(b)(2)(A) of the FD&C Act.

[8] See section 502(cc) of the FD&C Act (21 U.S.C. 352(cc)).

[9] See section 582(b)(4)(i)(II) of the FD&C Act.

by the manufacturer and who submits a request for verification to the manufacturer,[10] and (3) verify the product identifier on each package or sealed homogenous case of such product that they intended to further distribute as a saleable return.[11] In addition, this draft guidance addresses the requirements for wholesale distributors, dispensers, and repackagers related to engaging in transactions involving product with a product identifier[12] and product verification.[13] Lastly, this draft guidance addresses the requirements for wholesale distributors and repackagers related to saleable returns.[14]

The compliance policy set forth in this draft guidance applies only to the requirements regarding product identifiers described above. In brief, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of products intended to be introduced in a transaction into commerce before November 26, 2018. This represents a one year delay in enforcement of the requirement for manufacturers to affix or imprint product identifiers. For the products that manufacturers introduce in a transaction into commerce before November 26, 2018, without a product identifier, FDA also does not intend to take action against manufacturers who do not use a product identifier to verify such product at the package level.

FDA recognizes that downstream trading partners of manufacturers may wish to acquire product that was first introduced in a transaction into commerce by the manufacturer between November 27, 2017, and November 26, 2018, and does not have a product identifier. Therefore, this draft guidance addresses responsibilities of downstream trading partners as well. In that regard, FDA does not intend to take action against a repackager, wholesale distributor, or dispenser that engages in a transaction involving such product, regardless of when such a transaction occurs, except where a repackager's transaction triggers an independent responsibility to affix or imprint a product identifier. Furthermore, FDA does not intend to take action against a wholesale distributor, repackager or dispenser who does not verify the product identifier for such product. Lastly, FDA does not intend to take action against a repackager or wholesale distributor who does not verify the product identifier on each package or sealed homogenous case of such product that they intended to further distribute as a saleable return.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency'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 Agency guidances means that something is suggested or recommended, but not required.

[10] See section 582(b)(4)(C) of the FD&C Act.
[11] See section 582(b)(4)(E) of the FD&C Act.
[12] See section 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the FD&C Act.
[13] See section 582(c)(4), (d)(4), and (e)(4) of the FD&C Act.
[14] See section 582(c)(4)(D) and (e)(4)(E) of the FD&C Act.

II. BACKGROUND

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act. This section established product tracing, product identifier, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of a product through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 is a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. 331(t)).

An important requirement of the product tracing scheme outlined in the DSCSA is the product identifier. Section 582 requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier in both a human-readable form and on a machine-readable data carrier. The product identifier includes the product's standardized numerical identifier,[15] lot number, and expiration date. Manufacturers are required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce no later than November 27, 2017. Repackagers are required to do the same no later than November 27, 2018.[16]

III. COMPLIANCE POLICY FOR REQUIREMENTS RELATED TO THE PRODUCT IDENTIFIER

FDA has received comments and feedback from manufacturers and other trading partners expressing concern with industry-wide readiness for implementation of the product identifier requirements for manufacturers. Specifically, stakeholders have described challenges with implementation of product identifier requirements due to: (1) a limited number of vendors that that have the expertise to provide solutions related to information technology systems for data management or specific equipment for packaging or manufacturing lines, and (2) capabilities and readiness of contract facilities that perform manufacturing operations on behalf of the manufacturer. Given the concerns expressed, FDA recognizes that some manufacturers may need additional time beyond November 27, 2017, to ensure that products are properly labeled with a product identifier. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA has adopted the compliance policy set forth below.

[15] *Standard numerical identifier* is defined in section 581(20) of the FD&C Act as a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

[16] See section 582(e)(2)(A)(i) of the FD&C Act.

A. Compliance Policy for Manufacturers

Under section 582(b)(2)(A) of the FD&C Act, manufacturers are required to "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce" beginning not later than November 27, 2017. As a result, FDA expects that, under the statute any package or homogenous case of product that is introduced in a transaction into commerce by a manufacturer as of November 27, 2017, must be encoded with a product identifier. For the purpose of this draft guidance, we consider a product to be "introduced in a transaction into commerce" when the manufacturer first engages in a transaction involving that product.

Additionally, section 582(b)(4) of the FD&C Act requires that a manufacturer verify the product at the package level, including the standardized numerical identifier, which is part of the product identifier, when they determine that product in their possession or control is suspect or they receive a verification request from FDA.[17] A manufacturer is also required, upon receiving a request from an authorized trading partner that believes a product in its possession or control was manufactured by the manufacturer, to verify whether the product identifier affixed or imprinted on the product in such trading partner's possession or control corresponds to the product identifier affixed or imprinted by the manufacturer.[18] Manufacturers also must verify a product identifier on a saleable returned product before the manufacturer further distributes such product.[19]

1. Affixing or Imprinting Product Identifiers to Each Package or Homogenous Case of Product by Manufacturers

FDA does not intend to take action against manufacturers who do not, prior to November 27, 2018, affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce as required by section 582(b)(2)(A) of the FD&C Act.

2. Verification of Packages or Homogenous Cases of Product Without Product Identifiers by Manufacturers

As explained above, section 582(b)(4) of the FD&C Act establishes several requirements for manufacturers relating to the verification[20] of product identifiers that take effect on November 27, 2017. Under the policy outlined in this draft guidance, FDA does not intend to take action against a manufacturer that does not verify the product identifier in instances where such verification is required by section 582(b)(4) because the package or homogenous case does not bear a product identifier. Specifically, beginning November 27, 2017, FDA does not intend to

[17] See section 582(b)(4)(A)(i)(II) of the FD&C Act.
[18] See section 582(b)(4)(C) of the FD&C Act.
[19] See section 582(b)(4)(E) of the FD&C Act.
[20] *Verify* is defined in section 581(28) of the FD&C Act.

take action against a manufacturer who initially introduces product in a transaction into commerce without a product identifier between November 27, 2017, and November 26, 2018, and:

- does not verify product without a product identifier, at the package level, in situations where such verification is required by section 582(b)(4)(A)(i)(II) of the FD&C Act (i.e., the manufacturer has determined that such product is a suspect product or it has received a verification request for such product from the FDA);
- does not, upon receiving a request from an authorized trading partner, verify a product without a product identifier, as required by section 582(b)(4)(C) of the FD&C Act (i.e., the manufacturer has received a request for verification from an authorized trading partner that is in possession or control of a product that such trading partner believes to be manufactured by such manufacturer); or
- does not verify a package or sealed homogenous case of product without a product identifier that is intended for further distribution as a saleable returned product, as required by section 582(b)(4)(E) of the FD&C Act.

A manufacturer must still validate any applicable transaction history and transaction information in its possession if the manufacturer has determined that a product in its possession or control is a suspect product or if the manufacturer receives a verification request from the FDA or an authorized trading partner that is in possession or control of such product.[21]

Moreover, this compliance policy applies solely to product without a product identifiers that was first introduced in a transaction into commerce by a manufacturer between November 27, 2017, and November 26, 2018, and the requirements for manufacturers to verify the product identifier on such products as described in section 582(b)(4)(A)(i)(II), (b)(4)(C), and (b)(4)(E) of the FD&C Act. The compliance policy does not apply to any other provisions of section 582(b)(4). If a product has a product identifier, FDA expects manufacturers and downstream trading partners to use it in verification.

B. Compliance Policy for Repackagers, Wholesale Distributors, and Dispensers

After products with product identifiers are introduced in a transaction into commerce, the requirements for how other trading partners engage in transactions involving such products and use the product identifier are phased-in over 3 years. Beginning November 27, 2018, repackagers are generally required by section 582(e)(2)(A)(iii) of the FD&C Act to engage only in transactions involving products that bear a product identifier. Parallel requirements go into effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020, respectively, under section 582(c)(2) and (d)(2). Repackagers, wholesale distributors, and dispensers, starting November 27, 2018, November 27, 2019, and November 27, 2020, respectively, are required to verify product in certain circumstances at the package level, including the standardized numerical identifier, under section 582(e)(4)(A)(i)(II), (c)(4)(A)(i)(II),

[21] See section 582(b)(4)(A)(i)(II) and (b)(4)(C) of the FD&C Act.

and (d)(4)(A)(ii)(II). For a saleable returned product that wholesale distributors or repackagers intend to further distribute, the wholesale distributor or repackager must verify the product identifier, including the standardized numerical identifier, of each package or sealed homogenous case of such product, under section 582(c)(4)(D) and (e)(4)(E), respectively.

1. Engaging in Transactions Involving Product Without a Product Identifier

FDA notes that there may be product in the supply chain that was introduced into the pharmaceutical supply chain by a manufacturer between November 27, 2017, and November 26, 2018, and that does not contain a product identifier affixed or imprinted on the package and/or homogeneous case of product by the manufacturer. FDA does not intend to take action against:

- any repackager who, on or after November 27, 2018, accepts ownership of such product in a transaction, even though it lacks a product identifier, as addressed by section 582(e)(2)(A)(iii) of the FD&C Act;
- any wholesale distributor who, on or after November 27, 2019, engages in a transaction involving such product, even though it lacks a product identifier, as addressed by section 582(c)(2) of the FD&C Act; or
- any dispenser who, on or after November 27, 2020, engages in a transaction with such product, even though it lacks a product identifier, as addressed by section 582(d)(2) of the FD&C Act.[22]

This compliance policy does not affect the requirement that begins November 27, 2018, for repackagers to affix or imprint a product identifier on each package or homogenous case of product intended to be introduced in a transaction into commerce.[23] Consequently, beginning November 27, 2018, wholesale distributors and dispensers who purchase products from a repackager should ensure that they bear product identifiers.

2. Verification of Packages or Homogenous Cases of Product Without Product Identifiers by Repackagers, Wholesale Distributors, and Dispensers

FDA recognizes that packages and homogenous cases of product introduced in a transaction into commerce by a manufacturer between November 27, 2017, and November 26, 2018, without a product identifier will not be able to be verified using a product identifier at the package level by trading partners due to the products' lack of a product identifier. Therefore, FDA does not intend to take action against:

[22] This compliance policy regarding the requirement under section 582(d)(2) of the FD&C Act for dispensers to engage in transactions only involving product only if such product is encoded with a product identifier beginning not later than November 27, 2020, applies to dispensers as defined in section 581(3) of the FD&C Act, which includes pharmacies or licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.

[23] See section 582(e)(2)(A)(i) and (iii) of the FD&C Act.

- any repackager who does not use a product identifier to verify such product at the package level, including the standardized numerical identifier, beginning November 27, 2018, as required by section 582(e)(4)(A)(i)(II) of the FD&C Act;

- any wholesale distributor who does not use a product identifier to verify such product at the package level, including the standardized numerical identifier, beginning November 27, 2019, as required by section 582(c)(4)(A)(i)(II) of the FD&C Act; or

- any dispenser who does not verify that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product, beginning November 27, 2020, as required by section 582(d)(4)(A)(ii)(II) of the FD&C Act.[24]

However, repackagers, wholesale distributors, and dispensers must still validate any applicable transaction history and transaction information for such product that is in their possession and otherwise investigate the product to determine if it is suspect; the compliance policy does not extend to these requirements.[25] Similarly, where product does have a product identifier, FDA expects trading partners to use it in verifying product.

3. Saleable Returns by Wholesale Distributors or Repackagers

A wholesale distributor or repackager may receive a returned product without a product identifier if the returned product was introduced in a transaction into commerce by a manufacturer prior to November 27, 2018. For these saleable returned products, FDA does not intend to take action against:

- any wholesale distributor who does not verify the product identifier of a saleable returned package or sealed homogenous case of such product without a product identifier that is intended for further distribution, as required by section 582(c)(4)(D) of the FD&C Act; or

- any repackager who does not verify the product identifier of a saleable returned package or sealed homogeneous case of such product without a product identifier that is intended for further distribution, as required by section 582(e)(4)(E) of the FD&C Act.

[24] Under section 582(d)(5) of the FD&C Act, licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice are exempt from the dispenser requirements for verification described in section 582(d)(4) of the FD&C Act.

[25] See section 582(b)(4)(A)(II), (c)(4)(A)(II), (d)(4)(A)(III) and (e)(4)(A)(II) of the FD&C Act.

4. Documentation of the Date of Introduction in a Transaction Into Commerce

The compliance policy described in this draft guidance for packages and homogeneous cases of products only applies to product without a product identifier that is introduced by a manufacturer in a transaction into commerce between November 27, 2017, and November 26, 2018. Trading partners who believe that product may be subject to this compliance policy should take steps to determine that the product was introduced in a transaction into commerce by the manufacturer in this time frame. FDA recommends that a trading partner make such a determination for a product without a product identifier based on the following:

- At least one of the transaction information documents that compose the transaction history for the product describes an initial transaction date from the manufacturer that occurs between November 27, 2017, and November 26, 2018; or

- There is other documentary evidence created by a trading partner in the ordinary course of business and containing a product description that matches the package or homogenous case of product that is not labeled with a product identifier. In addition, this other documentary evidence should contain a date from which it can be determined that the product was introduced in a transaction into commerce by the manufacturer between November 27, 2017, and November 26, 2018. Examples of such documents may include, but are not limited to, bills of lading, commercial invoices, and shipping invoices.

C. Compliance Policy Regarding Product Misbranded for Failure To Bear a Product Identifier

Under this compliance policy, FDA does not intend to take action against a manufacturer, repackager, or wholesale distributor who engages in prohibited acts involving products that are misbranded based on lack of product identifier alone, where the package and/or homogeneous case of product that lacks a product identifier was introduced in a transaction into commerce by a manufacturer between November 27, 2017, and November 26, 2018.

As previously stated, a package or homogeneous case of product that does not have a product identifier as required under section 582 of the FD&C Act is misbranded under section 502(cc) of the FD&C Act. The FD&C Act describes several prohibited acts involving misbranded drugs, which include introduction or delivery for introduction into interstate commerce of a drug that is misbranded, receipt in interstate commerce of a misbranded drug and the delivery or proferred delivery thereof, and the doing of an act that causes a drug to become misbranded while held for sale after shipment in interstate commerce.[26]

[26] See, e.g., section 301(a), (c), and (k) of the FD&C Act.

IV. RELATIONSHIP TO "GRANDFATHERED" PRODUCTS UNDER SECTION 582(a)(5) OF THE FD&C ACT

This compliance policy addresses products a manufacturer introduces in a transaction into commerce without product identifiers between November 27, 2017, and November 26, 2018. In the future, FDA intends to issue additional guidance that will outline FDA's current thinking on the "grandfathering product" provision of section 582(a)(5)(A) of the FD&C Act regarding products not labeled with a product identifier that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582. In that guidance, FDA intends to address the relationship of the compliance policy set forth in this guidance with "grandfathered" products.

Attachment 2

CURES Data

Total Number Registered			
	May 2017	**June 2017**	**July 2017**
Prescribers	128,715	129,289	129,880
Dispensers	40,006	40,097	40,185
Total*	171,771	172,430	173,100
Pharmacists	35,548	35,715	35,857

*Includes all entities registered in CURES.

Number of Patient Activity Reports (PAR) Run			
	May 2017	**June 2017**	**July 2017**
Prescribers	373,401	432,537	407,665
Dispensers	571,024	635,920	626,212
Total*	948,299	1,072,364	1,037,291
Pharmacists	568,685	633,626	624,413

*Includes all entities that are authorized to access CURES.

Number of Times Accessed CURES			
	May 2017	**June 2017**	**July 2017**
Prescribers	184,337	201,464	184,348
Dispensers	279,685	299,883	289,748
Total*	466,788	504,198	476,548
Pharmacists	278,847	299,005	288,980

*Includes all entities that are authorized to access CURES.

Note: The totals for July are not complete.