

POLICY AND PROCEDURES

OFFICE OF COMPLIANCE

CDER Barcode Inquiries

Table of Contents

PURPOSE.....1
BACKGROUND1
POLICY.....2
RESPONSIBILITIES3
PROCEDURES4
REFERENCES.....6
DEFINITIONS6
EFFECTIVE DATE.....7
CHANGE CONTROL TABLE.....7

PURPOSE

This MAPP establishes the Center for Drug Evaluation and Research (CDER) procedures for receipt, evaluation, and management of inquiries regarding barcoding requirements under the Drug Supply Chain Security Act (DSCSA) and 21 CFR 201.25. This MAPP also outlines the responsibilities of the Barcode Labeling Workgroup, which is comprised of staff from both CDER and the Center for Biologics Evaluation and Research (CBER).

BACKGROUND

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into law. Section 202 of the DSCSA added new sections 581 and 582 to the Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee-1), which establish product identifier requirements for a standardized graphic in both human- and machine-readable form to be affixed or imprinted on packages (i.e., 2-dimensional (2D) data matrix barcode) and homogeneous cases (i.e., 2D data matrix barcode or linear barcode).

Pursuant to section 582(b)(2)(A) of the FD&C Act, manufacturers have no later than 4 years after the date of enactment of the DSCSA 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.” Repackagers have 5 years to meet the same product identifier requirement under 582(e)(2)(A). Therefore, manufacturers have until November 27, 2017, and repackagers until November 27, 2018, to meet the product identifier requirements. In June 2017, FDA published a draft guidance “Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy”, in which FDA describes its intention regarding the enforcement of certain product identifier requirements under the Drug Supply Chain Security Act. As described in the draft guidance, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of products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 27, 2018.

The linear barcode requirements under 21 CFR 201.25 are still in effect and apply to additional FDA-regulated products and packaging in some instances.¹

POLICY

CDER’s Office of Compliance (OC) policy is to provide prompt and accurate responses to any inquiry regarding barcode labeling issues, while maintaining appropriate confidentiality related to other stakeholders in the drug review process, including the existence of and information contained in New Drug Applications (NDAs), Biologics License Applications (BLAs), Abbreviated New Drug Applications (ANDAs), and information contained in a referenced Drug Master File (DMF). Inquiries are to be generally responded to within ten (10) business days of receipt, or longer if the issue is complex and/or requires consultation with the Office of the Chief Counsel (OCC) or other FDA units outside CDER.

This MAPP acknowledges that CBER is responsible for responding to all inquiries regarding CBER-regulated products. CDER staff (as described below under Inquiry Assignment Lead Responsibilities) will determine if an inquiry is requesting information concerning products regulated by CBER. If so, CDER staff will forward the inquiry within two working days to CBER’s Office of Communication, Outreach and Development at: ocod@fda.hhs.gov.

¹ In the Federal Register of February 26, 2004 (69 FR 9120), FDA published a final rule requiring certain human drug and biological product labels to have a linear barcode that contains, at a minimum, the drug’s NDC number (21 CFR 201.25). Manufacturers, repackers (also known as “repackagers”), relabelers, and private label distributors of human prescription drug products, biological products, and over-the-counter (OTC) drug products that are dispensed pursuant to an order and are commonly used in hospitals are subject to the linear barcode requirement. For further information on barcode requirements under the DSCSA and 21 CFR 201.25, see FDA’s Guidance: “Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers, Guidance for Industry.”

As set forth below, the administrator of the CDER Barcode Questions Mailbox will communicate with the Barcode Labeling Workgroup as appropriate, and provide responses to inquiries received by CDER regarding barcode issues.

None of the communication described in this MAPP should be construed as final Agency action.

RESPONSIBILITIES

Office of Drug Security, Integrity, and Response (ODSIR) Subject Matter Expert:

- Provide expert knowledge of the DSCSA and 21 CFR 201.25 to the Inquiry Assignment Lead and Barcode Labeling Workgroup.
- Work with the Inquiry Assignment Lead to ensure the accuracy and consistency of draft and final responses to inquiries.
- Work with the Inquiry Assignment Lead to obtain OC management's review of inquiries that involve a new, novel, controversial, and/or complex interpretation of the DSCSA and/or 21 CFR 201.25. OC management will be consulted on such issues prior to seeking input from the Barcode Labeling Workgroup.
- Along with the Inquiry Assignment Lead, periodically evaluate the inquiries and responses to identify guidance needs and gaps in understanding, and to evaluate the effectiveness of this MAPP.

Barcode Labeling Workgroup: Comprised of CDER and CBER staff members, this workgroup evaluates and proposes policies, interpretations, and regulations for barcode labeling issues under the DSCSA. Specific to this MAPP, the Barcode Labeling Workgroup:

- Provide feedback to the Inquiry Assignment Lead regarding inquiries and coordinate with the Inquiry Assignment Lead to resolve all inquiry-related matters.
- Identify potential cross-cutting Agency issues that may impact the Agency's response to inquiries.
- Refer all inquiries concerning barcode labeling for CDER-regulated products to the CDERBarcodeQuestions@fda.hhs.gov mailbox. Refer all inquiries regarding CBER-regulated products to the ocod@fda.hhs.gov mailbox.

Inquiry Assignment Lead:

- Manage the receipt, assignment, distribution, and response of all internal and external inquiries received through the inquiry mailbox CDERBarcodeQuestions@fda.hhs.gov.
 - Determine if an inquiry is related to a product regulated by CBER. If so, forward the inquiry to CBER's Office of Communication, Outreach and Development (OCOD) at: ocod@fda.hhs.gov within two working days.
 - Consult with ODSIR Subject Matter Expert or their designee, as appropriate, and copy them on inquiry responses.
 - Convene the Barcode Labeling Workgroup to discuss inquiries that involve complex and/or cross-cutting issues within the Agency, as needed.
 - Ensure consistency and accuracy of inquiry responses.
 - Request review by OC management of any inquiry that requires a new, novel, controversial, and/or complex interpretation of the DSCSA and/or 21 CFR 201.25. OC management will be consulted on such issues prior to seeking input from the Barcode Labeling Workgroup.
 - Maintain completed inquiries in the "Archived" folder of the CDER Barcode Questions mailbox.
 - Periodically evaluate the inquiries and responses to identify guidance needs and gaps in understanding, and to evaluate the effectiveness of this MAPP.
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PROCEDURES

The following procedures will be used when responding to internal and external labeling inquiries.

Inquiry Assignment Lead will:

1. Monitor, or ensure the regular monitoring of the mailbox CDERBarcodeQuestions@fda.hhs.gov and respond to inquiries as appropriate. When unable at any point in time to handle inquiries for longer than ten (10) working days, ensure that an acting Lead can assume the responsibilities.
2. If an inquiry that requested information concerning products regulated by CBER was inadvertently not sent to CBER within two working days, forward the inquiry to CBER's Office of Communication, Outreach and Development at: ocod@fda.hhs.gov immediately.

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3. Request consults, as appropriate, with the ODSIR Subject Matter Expert or their designee.
 4. Request review and/or clearance by OC management of any inquiry that requires new, novel, controversial, and/or complex interpretation of the DSCSA.
 5. Coordinate internal discussions with the Barcode Labeling Workgroup, the ODSIR Subject Matter Expert, and/or OC/ODSIR Management when inquiries to the mailbox CDERBarcodeQuestions@fda.hhs.gov involve complex and/or cross-cutting issues within the Agency.
 6. Draft, finalize, and send consistent and accurate responses to inquiries from the mailbox CDERBarcodeQuestions@fda.hhs.gov. The following will be reviewed during the drafting of responses to ensure consistent and accurate responses:
 - Completed inquiries.
 - Existing regulations.
 - Existing policy.
 - FDA guidance documents.

Copy appropriate staff, as needed, on responses to inquiries.

7. Determine whether a question is beyond the scope of the CDER Barcode Inquiries system. If so, advise the inquirer that FDA/CDER is not able to provide detailed responses and the inquirer should consider retaining a consultant.
8. File completed responses in the appropriate “Archived” folder of the CDER Barcode Questions mailbox.
9. Evaluate inquiries to identify policy needs, and work with Barcode Labeling Workgroup to revise, replace, and/or finalize current policy documents, as appropriate.

ODSIR Subject Matter Expert will:

1. Upon request from the Inquiry Assignment Lead, research and provide expert knowledge and advice on DSCSA inquiries to the Inquiry Assignment Lead and Barcode Labeling Workgroup.
2. Upon request from the Inquiry Assignment Lead, provide feedback on draft and final responses, and request prompt corrections/clarifications of any misstatements or errors in draft and/or final responses.
3. Upon request from the Inquiry Assignment Lead, assist with review and/or clearance by OC management of any inquiry that requires new, novel, controversial, and/or complex interpretation of the DSCSA.

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4. In cooperation with the Inquiry Assignment Lead, evaluate inquiries to identify policy needs, and work with Barcode Labeling Workgroup to revise, replace, and/or finalize current policy documents, as appropriate.

Barcode Labeling Workgroup members will:

1. Upon request from the Inquiry Assignment Lead and/or the ODSIR Subject Matter Expert, discuss and provide feedback regarding inquiries to resolve matters that arise.
2. Upon request from the Inquiry Assignment Lead and/or ODSIR Subject Matter Expert, identify and discuss potential cross-cutting Agency issues that may impact Agency responses to inquiries.
3. Forward all inquiries concerning barcode labeling for CDER-regulated products to the CDERBar codeQuestions@fda.hhs.gov mailbox.

REFERENCES

1. FDA, 1938, Federal Food, Drug, and Cosmetic Act, revised.
2. FDA, 2013, Drug Supply Chain Security Act (DSCSA).

DEFINITIONS

Package under DSCSA – Under section 581(11)(A) of the FD&C Act, a package is defined as the “smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.”

Homogeneous Case under DSCSA – Under section 581(7) of the FD&C Act, a homogenous case is defined as “a sealed case containing only product that has a single National Drug Code number belonging to a single lot.”

Product Identifier under DSCSA – Under section 581(14) of the FD&C Act, the product identifier is defined 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.” The product identifier is specifically required to be a “2-dimensional data matrix barcode” for packages and a “linear or 2-dimensional data matrix barcode” for homogeneous cases, which can be verified using “human-readable or machine-readable methods.” Section 582(a)(9)(A)(i)-(ii) and 582(a)(9)(B) of the FD&C Act. The product identifier under the

DSCSA requires different elements from the linear bar code requirement at 21 CFR 201.25.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions