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Guidelines for Bar Coding in the Pharmaceutical Supply Chain

HDA

HDA GUIDELINES FOR BAR CODING IN THE PHARMACEUTICAL SUPPLY CHAIN

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The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

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SUMMARY OF REVISIONS

Below is a list of significant changes from the 2017 ***HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain:***

- Clarifies abbreviation and expiration date formats based on industry practice, updated guidance documents from the USP on labeling coming into effect in 2023 and the Food and Drug Administration (FDA) guidance documents.
- Addresses FDA final guidance, "Product Identifiers under the Drug Supply Chain Security Act – Questions and Answers," including human-readable NDC;
- Includes requirements for four data elements of a product identifier mandated by DSCSA;
- Provides recommendations for encoded elements, order of encoding and human-readable interpretation (HRI);
- Makes recommendations and specifications for inner-packs and corner-wraps, respectively;
- Updates partial/mixed case recommendations;
- Recommends use of UPC-A to comply with the bar code rule in retail settings;
- Includes updated links to the 2021 GS1 General Specification; and,
- Includes updated images and figures to display current recommendations, with a summary specifications table for serialized and non-serialized products.

INTRODUCTION

With increasing pressure to reduce healthcare costs and improve patient safety, there is a need to identify and refine how proven technologies are used to increase the efficiency of supply chain procurement, replenishment and logistics processes. These efforts will enhance the quality of patient care in the U.S. and around the world.

The 2022 edition of the *HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain* was developed by the HDA Bar Code Task Force based on strong industry consensus across major stakeholder segments. In 1993, HDA published the first bar coding guide, *Numerical and Automatic Identification of Drug Products*, providing instructions for pharmaceutical bar coding from the basic unit of sale (the stock keeping unit or SKU) to higher packaging levels, including inner packs, shipping cases and pallet loads. HDA guidance on bar coding has continued to evolve to stay current with technical, business and legal changes within the U.S. healthcare supply chain.[1] This publication was revised in 2017. HDA also published two "Quick Start Guidelines" for bar coding in the pharmaceutical supply chain in 2014 and 2016. The 2022 guidelines supersede the 2017 edition, the "Quick Start Guideline" and other versions of these documents.

The most important change necessitating the 2017 *HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain* was the passage of the Drug Quality and Security Act (DQSA), which was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S. These guidelines are intended to aid supply chain stakeholders in meeting the DSCSA requirements.

The DSCSA requires that each covered drug package and homogenous case bear a product identifier in machine- and human-readable formats that conforms to the standards developed by a widely recognized international standards development organization. The product identifier comprises the National Drug Code (NDC), a unique serial number, expiration date and lot number.

The 2022 revision continues to serve as an industry-wide voluntary guideline on the use of globally accepted GS1 system data structures and symbologies to comply with the DSCSA and convey the DSCSA-required product identifier. This update builds on lessons learned from implementation over the past four years. This revision provides detailed guidance on shipping case bar code label format, marking and placement, and it serves as a resource for more detailed primary and secondary sources of information on standards for bar codes to be used in the U.S. pharmaceutical supply chain. These revisions include changes in terminology; updated and expanded content, including additional information on GS1 standards; the DSCSA and suggested best practices; as well as additional label examples for serialized and non-serialized product.

Every effort has been made to maintain the logical foundation upon which previous editions were built and make the required label format changes straightforward to implement. Where legislation, regulations and guidance from previous versions remain relevant, we continue to include them.

1. Before this edition, the HDA bar code guidelines were updated in 2001, revised in 2005 (renamed the *HDMA Guidelines for Bar Coding in the Pharmaceutical Products Supply Chain*) and updated again in 2011 and 2017.

FOOD AND DRUG ADMINISTRATION (FDA) REQUIREMENTS AND GUIDANCE IMPACTING BAR CODING OF PHARMACEUTICALS

The NDC

Federal law requires that drug manufacturers register their establishments with FDA annually. These companies must submit a list of the drugs they manufacture, including each drug's National Drug Code (NDC) number.[2] FDA regulations in 21 C.F.R. Part 207 implement this requirement.[3]

The 10-digit NDC is the single, basic identifier for all forms of pharmaceutical products in the U.S. healthcare industry. It is a critical component of bar coding and serialization of pharmaceuticals. Pharmacy computer systems, third-party prescription claims processing and sales tracking, reporting and industry support services all use the NDC to identify, describe and pay for pharmaceuticals. Pharmacy providers must use the NDC for all Medicaid claims.[4] The NDC also is used for the monthly reporting of all incoming and outgoing controlled substance transactions and inventories.[5] From the manufacturer to the healthcare distributor to the provider, computer systems depend on the NDC to identify what is being ordered, paid, returned and credited.

Understanding the NDC's components and how it is incorporated into bar codes in compliance with international standards is discussed in the sections entitled, "Configuring the NDC in Bar Codes" and "The Product Identifier."

DSCSA

The DSCSA requires manufacturers affix or imprint a "product identifier" to each package and homogeneous case of a product the manufacturer intends to be introduced in a transaction into commerce.[6]

- A "product identifier" is "a standardized graphic that includes, in both a human-readable format 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 [SNI], lot number and expiration date of the product."[7]

2. § 510 of the Federal Food, Drug and Cosmetic (FDC) Act is codified at 21 U.S.C. § 360. All citations that follow to the FDC Act will first provide the relevant section of the FDC Act, followed by where that section is codified in the U.S. Code.

3. In August 2016, FDA amended the drug establishment and drug listing rule (21 C.F.R. Part 207) and the bar code rule (21 C.F.R. § 201.25) effective November 29, 2016 [81 Fed. Reg. 60169 (Aug. 31, 2016)]. Though there are many changes, FDA did not change the configuration of the NDC, nor how it is created and assigned. The *Federal Register* notice publishing the NDC and bar code final rules is available at https://www.federalregister.gov/documents/2016/08/31/2016-20471/requirements-for-foreign-and-domestic-establishment-registration-and-listing-for-human-drugs. The NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (Retrieved on May 3, 2017). The revised bar code rule reflecting this amendment (21 C.F.R. § 201.25) is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved May 17, 2017). FDA, however, is "running out of" NDC numbers that can be configured in the 10-digit format and so has begun policy development around expansion of the NDC to more digits. See e.g., 83 Fed. Reg. 38666 (Aug. 7, 2018, announcement of FDA public hearing on future format of NDC).

4. *Omnibus Budget Reconciliation Act of 1990*, Public Law 101-508, 101st Congress (1990). Retrieved from https://www.congress.gov/bill/101st-congress/house-bill/5835/text.

5. Drug Enforcement Administration, ARCOS Registrant Handbook (Revised August 1997). Retrieved from http://www.deadiversion.usdoj.gov/arcos/handbook/index.html.

6. § 582(b)(2)(A), § 21 U.S.C. § 360eee-1(b)(2)(A).

7. § 581(14), 21 U.S.C. § 360eee(14).

- The "'standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package[8] or homogeneous case[9]that is composed of the [NDC] corresponding to the specific product (including the particular package configuration), combined with a unique alphanumeric serial number of up to 20 characters."[10]

This requirement to affix or imprint the product identifier to each package and homogeneous case of a product intended to be introduced in a transaction into commerce went into effect on November 27, 2017. The compliance date was one year later on November 27, 2018, for repackagers.[11] On July 3, 2017, the FDA released a draft guidance[12] announcing that it would exercise a one-year period of enforcement discretion and that it did 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 homogeneous case of product intended to be introduced in a transaction into commerce. FDA did not propose extending this one-year delay for repackagers. The repackager date of compliance remained as November 27, 2018. FDA finalized the guidance on September 19, 2018, and all covered products and homogenous cases packaged or repackaged after November 27, 2018, must bear a product identifier.[13]

Further information about the product identifier and encoding it into a 2D Data Matrix is included in the section entitled, "The Product Identifier."

FDA Bar Code Rule

FDA's bar code rule, 21 C.F.R. § 201.25,[14](14) requires an encoded, standardized linear bar code containing the NDC number on human prescription drugs, biologics[15] and non-prescription, over-the-counter (OTC) drugs that are dispensed and commonly used in hospitals. These drug products must have a bar code that contains at least the appropriate drug's NDC number in a linear bar code that meets GS1, Health Industry Business Communications Council (HIBCC) standards, or another standard or format that has been approved by FDA.[16]

8. A "'package' means 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" [§ 581(11)(A), 21 U.S.C. § 360eee(11)(A)]. An "'individual saleable unit' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser" [§ 581(11)(B), 21 U.S.C. § 360eee(11)(B)].

9. A "homogeneous case" is a sealed case containing only product that has a single [NDC] number belonging to a single lot" [§ 581(7), 21 U.S.C. § 360eee(7)].

10. § 581(20), 21 U.S.C. § 360eee(20).

11. § 582(b)(2)(A), § 21 U.S.C. § 360eee-1(b)(2)(A) and § 582(e)(2)(A), § 21 U.S.C. § 360eee-1(e)(2)(A).

12. Draft Guidance for Industry, Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy." 82 Fed. Reg. 30868 (July 3, 2017) ("Product Identifier Compliance Policy"). The draft guidance is available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf (retrieved July 11, 2017).

13. "Final Guidance for Industry, Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy." 83 Fed. Reg. 47625 (Sept. 20, 2018) ("Product Identifier Compliance Policy"). The final guidance is available at https://www.fda.gov/media/106198/download (retrieved October 29, 2021).

14. In August 2016, FDA amended the bar code rule effective November 29, 2016 [81 Fed. Reg. 60169, 60177 (Aug. 31, 2016)]. This new, 2016 bar code rule is not yet available on government websites. The 2015 version of the FDA bar code rule is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.25 (Retrieved May 3, 2017). The most current version of the rule, as of May 2017, is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved May 3, 2017).

15. 21 C.F.R. § 610.67 applies the standards of 21 C.F.R. § 201.25 to biologics. A separate FDA rule mandating standardized data structures and bar codes on blood and blood products is beyond the scope of this document [see 21 C.F.R. § 606.121(b)(13)].

16. The older version of the rule had specified only GS1 or HIBCC standards. In its August 2016 amendment to the bar code rule, FDA added that, effective November 29, 2016, the agency could, if it elected to do so, approve bar code standards and formats other the GS1 or HIBCC standard [81 Fed. Reg. at 60177]. The revised bar code rule reflecting this amendment [21 C.F.R. § 201.25,(c)(1)] is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved May 17, 2017).

The bar code must appear on the drug's label[17] and be surrounded by sufficient blank space so that it can be scanned correctly.[18] A drug's label is defined in the FDC Act as a display of written, printed or graphic matter upon the immediate container of any article; any requirement, such as the bar code, that must appear on the immediate container, also must appear on the article's outside container or wrapper, or be easily legible through the outside container or wrapper.[19]

The "Two-dimensional (2D) Bar Code" section discusses linear bar codes in further detail.

GUIDELINE RECOMMENDATION

Pharmaceutical manufacturers have typically used UPC-A to comply with current bar code rules. As packaging is redesigned to account for additional information required by DSCSA encoded within an ISO/IEC Data Matrix, these guidelines recommend that manufacturers continue to rely on UPC-A in retail settings, even if reduced magnification or truncation is required due to space constraints. Reduced size has been shown to be more easily read by supply chain partners based on current hardware and configuration within wholesale distribution and retail channels. The GS1 DataBar and GS1 DataBars stacked are frequently used within and institutional and hospital settings. Trading partners should be mindful of where their products will be utilized to ensure readability

FDA Final Guidance, "Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages"

FDA issued a final guidance, "Product Identifiers Under the Drug Supply Chain Security Act – Questions and Answers" ("Product Identifier Final Guidance").[20] FDA states that this guidance "is intended to address anticipated questions regarding product identifiers … for packages and homogenous cases of certain drug products" which had to be affixed or imprinted "to each package and homogenous case of a product intended to be introduced in a transaction."[21] As discussed, the requirement to affix or imprint product identifiers on drug packages and homogenous cases applied to products packaged after November 27, 2017, for manufacturers (though FDA granted a year of enforcement discretion) and November 27, 2018, for repackagers. FDA issued the guidance in draft in September 2018, approximately two months before the requirement went into effect for all covered prescription products; the Product Identifier Final Guidance was issued two-and-a-half years after the effective date of the product identifier requirement and the expiration of FDA's enforcement discretion.

Given the late issuance of the Product Identifier Final Guidance and its earlier draft, for guidance on assigning product identifiers, the supply chain turned to the language of the law and FDA's previous, 2010 final guidance, "Standards for Securing the Drug Supply Chain – Standardized Numerical Identification

17. 21 C.F.R. § 201.25(c)(2).

18. 21 C.F.R. § 201.25(c)(1)(i). The revised bar code rule [21 C.F.R. § 201.25] is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved May 17, 2017).

19. § 201(k), 21 U.S.C. § 321(k) (definition of "label").

20. "Final Guidance for Industry, Product Identifiers Under the Drug Supply Chain Security Act – Questions and Answers." [86 Fed. Reg. 30058 (June 2021)]. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifiers-under-drug-supply-chain-security-act-questions-and-answers on October 30, 2021. A guidance is not legally binding or enforceable but reflects FDA's current thinking on a topic.

21. Product Identifier Final Guidance at 1 (citations and internal quotations omitted).

for Prescription Drug Packages"[22] ("SNI Final Guidance"). The DSCSA requires that a product identifier be 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."[23] The SNI Final Guidance refers to the combination of NDC and a unique serial number as a "serialized National Drug Code" or "sNDC." The FDA SNI Guidance is consistent with the DSCSA, which similarly defines the SNI as the NDC combined with a unique alphanumeric serial number of up to 20 characters.

The DSCSA and the SNI Final Guidance are further aligned in that the SNI Final Guidance explains that an sNDC may be presented within a Global Trade Item Number® or GTIN®, which can be serialized using the GS1 Application Identifier AI(21)[24] to create a serialized GTIN (sGTIN). The SNI Final Guidance also recognizes that the GTIN is a global standard for item and object identification and that it has been established by GS1, a consensus-based, not-for-profit international standards organization.

Creating an sGTIN from a drug's NDC to build a product identifier is discussed further in "Serializing the GTIN," found in the section on "The Product Identifier." All manufacturers and repackagers are currently serializing at the GTIN level, which has the NDC embedded within it.

The Product Identifier Final Guidance has created confusion regarding the presentation of the human-readable portion of the product identifier. Question and Answer 5 of the Product Identifier Final Guidance states:

> Can the GS1 Global Trade Identification Number (GTIN) be used in place of the NDC to comply with the requirements for a human-readable NDC as part of the product identifier?
>
> We recommend against using the GTIN in place of a separate NDC in the human-readable portion of the product identifier.

This "recommendation" in the Product Identifier Final Guidance appears to require the presentation of the NDC in the human-readable portion of the product identifier, with presentation of the GTIN being optional. If this is a correct interpretation of the Product Identifier Final Guidance, it results in potential violation of the DSCSA, non-conformance with international standards, possible risks to patient safety and supply chain confusion.

The NDC is not compliant with or generated pursuant to international standards, as required by the DSCSA; only the GTIN in the product identifier conforms to GS1 international standards. The combination of NDC and serial number will not uniquely identify the product. Only the GTIN and serial number combination uniquely identifies a product. This is because, unlike the GTIN, the NDC does not change depending upon packaging configurations of the same product (e.g., a case, and a carton within in it all have the same NDC as the individual saleable unit of product itself). Including only the NDC in the human- or machine-readable product identifier and not the GTIN means that the product is no longer uniquely identified.

Having a human-readable version of the product identifier is necessary so that if the machine-readable product identifier cannot be scanned and read, trading partners can use the human-readable portion to support their distribution, receiving and patient dispensing processes — and can trace the unique item in the event of a product problem. Using only the NDC and not the GTIN in the human-readable product identifier means the product cannot be uniquely identified and traced.

22. "Final Guidance for Industry – Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages." [75 FR 15440 (March 2010)]. Retrieved from. http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm on October 30, 2021.

23. § 581(14), 21 U.S.C. § 360eee(14).

24. The AI, which precedes each data element, is an all-numeric "flag" designated by GS1 to identify each of the more than 100 distinct data elements in use throughout the global GS1 System. AIs are shown in the human-readable text within parentheses. A table of GS1 AIs is available at https://www.gs1-128.info/application-identifiers/ (accessed October 30, 2021).

The Product Identifier Final Guidance does state that, in addition to the NDC, manufacturers and repackagers also might affix or imprint the human-readable GTIN on the package label, in close proximity to product identifier elements. The agency does not object to use of the GTIN in the machine-readable product identifier.

GUIDELINE RECOMMENDATION

These guidelines ***do not recommend*** that manufacturers and repackagers omit the GTIN in the human-readable portion of the product identifier as its omission may separately violate the DSCSA and could create difficulties for downstream trading partners and potentially even compromise patient safety. These guidelines strongly urge manufacturers and repackagers to continue to use the GTIN in their product identifiers. Manufacturers and repackagers also may elect to add the NDC to the human-readable portion of the product identifier in addition to the GTIN; if manufacturers and repackagers elect to not include the NDC in the human-readable portion of the product identifier, these guidelines recommend that the NDC number, in its three-segment format, appear elsewhere on the product label.

Linear and 2D Bar Codes for FDA-Regulated Products

Unless otherwise exempt, **prescription drugs** and biologics:

- Must have NDC numbers;
- Are subject to the bar code rule and must have a linear bar code; and,
- Must have a DSCSA product identifier on each package[25] and each homogeneous case.[26]

OTC drugs:

- Must have NDC numbers (manufacturers generally assign NDCs to the packaging level that is intended to be purchased by the retail customer);
- Are subject to the bar code rule and must have a linear bar code if they are dispensed and are commonly used in hospitals; and,
- Are not required to have a DSCSA product identifier.

Bar coding and identifiers for blood and blood products, medical devices and animal drugs, and combination products (e.g., a prescription drug and medical device) are beyond the scope of these guidelines.

25. In § 581(11), 21 U.S.C. § 360eee(11), a "package" is "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." An "individual saleable unit" is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser."

26. In § 581(7), 21 U.S.C. § 360eee(7), a "homogeneous case" is "a sealed case containing only product that has a single National Drug Code number belonging to a single lot."

CONFIGURING THE NDC IN BAR CODES

Decoding the 10-Digit NDC

As discussed in the previous section, the NDC, by FDA regulation,[27] is a 10-digit numeric code.

The NDC consists of three numeric fields of information. The FDA assigns the labeler portion of the code (the first or left-most field). The labeler (the organization controlling the product, typically the manufacturer or repackager) assigns both the product identification portion of the code (second or middle field) and trade/package portion (third or right-most field) according to format standards specified by FDA and adopted by the manufacturer or repackager.

The FDA originally developed and assigned the NDC labeler identification portion of the code as a fixed-length, four-digit field, starting at 0002. The system was designed not to exceed a labeler identification of 0999. When it became apparent to the FDA Drug Listing Branch that the number of companies applying for labeler codes would exceed 999, they redefined the NDC to also include five-digit manufacturer/labeler identification codes. The numbering for these labelers starts at 10000. To avoid ambiguity with NDC labeler identification codes in this higher range, labeler identification codes in the range of 1000-9999 are not assigned.[28]

The FDA-prescribed NDC is presented in one of three hyphenated, human-readable formats; these are referred to as "4-4-2," "5-3-2" or "5-4-1."

The first field of four or five digits identifies the manufacturer/repackager of the product. The next field of three or four digits identifies the product, dosage form and strength. The final field of one or two digits identifies the individual trade/package size or SKU. Labelers assigned a five-digit identifier can choose either a "3-2" or a "4-1" product and package size code structure. This means that the labeler can have up to 1,000 products with 100 trade package sizes for each one; or 10,000 products with 10 trade package sizes for each one. Once selected, labelers must maintain the selected "5-3-2" or "5-4-1" structure for all products using this labeler code.[29]

Under the NDC rule, each finished drug product must have a unique NDC number. A finished drug product means a finished dosage form (e.g., tablet, capsule or solution) that contains at least one active pharmaceutical ingredient in finished package form suitable for distribution to pharmacies, hospitals or other sellers or dispensers of the drug product to patients or consumers.[30]

27. 21 C.F.R. Part 207; the NDC rule, as recently amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).

28. FDA has recognized that eventually, likely in 10 or more years, the supply of five-digit labeler codes will be exhausted, which will necessitate possible creation of six-digit labeler codes or other changes to the NDC. See, e.g., 83 Fed. Reg. 38666 (Aug. 7, 2018, FDA convening of public meeting and request for comments on future format of NDC); "Revising the National Drug Code Format and Drug Labeling Barcode Requirements, Notice of Proposed Rulemaking," identified in the Department of Health and Human Services regulatory agenda, available at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0910-AI52 (retrieved October 30, 30212021).

29. The *Federal Register* notice publishing the NDC final rule is available at https://www.federalregister.gov/documents/2016/08/31/2016-20471/requirements-for- foreign-and-domestic-establishment-registration-and-listing-for-human-drugs. The NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).

30. 21 C.F.R. § 207.33; the NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).

Each registrant must list with the FDA, by NDC number, each drug that it manufactures, repacks, relabels or salvages for commercial distribution.[31] Commercial distribution refers to any distribution of a human drug except for investigational uses and internal or interplant transfer between registered establishments under common ownership and control.[32] Each domestic registrant must list each such drug with FDA regardless of whether the drug enters interstate commerce.[33]

A common practice for prescription pharmaceuticals has been to assign the NDC to the level at which the drug's package insert is provided. It also may be appropriate according to FDA regulations to assign a separate NDC (one with a different package code/"package size") to a unit-dose or unit-of-use package of the same drug. Some pharmaceutical labelers follow this practice; others do not.

For OTC products, the NDC generally has been assigned to the level that is intended to be purchased by the retail customer. For those drugs packaged for institutional use, under the FDA bar code rule, it also may be appropriate to assign a distinct NDC to the unit-dose or unit-of-use level if the drug is offered in that package configuration.

The 2016 FDA NDC rule updated when changes to a drug necessitate assigning a new NDC, such as a change in the drug's proprietary name, active ingredient, dosage form or packaging configuration.[34] Any new NDC number or change to an existing one should be communicated to FDA as required by regulation. Changes also should be clearly and promptly communicated throughout the supply channel, to trading partners and compendia database providers (such as First Databank, Medi-Span, Micromedex, etc.). This will ensure that the new numbers are included in the drug files made available by these clinical support vendors and that trading partners will be able to purchase, sell, and dispense the product.

FDA's "Guidance for Industry, Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing,"[35] provides helpful information regarding the formatting and submission of NDCs to FDA.

Whenever an NDC is printed in human-readable form, all leading, embedded and trailing zeros must be included and each of the three fields (labeler, product and package size) should be separated by a hyphen. The hyphens appear in the human-readable text only and are not currently encoded in the linear bar code, 2D Data Matrix or any other standardized data structures. While not currently in practice, AI715 can be utilized to encode the NDC, the hyphens may then be encoded to explicitly denote labeler, product and package size.

31. 21 C.F.R. § 207.41(a); the NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).
32. 21 C.F.R. § 207.1(a); the NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).
33. 21 C.F.R. § 207.41(a); the NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).
34. 21 C.F.R. § 207.35; the NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).
35. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf (retrieved on October 30, 2021).

Importance of NDC Format

In certain segments of the pharmaceutical industry, 10-digit NDCs are converted into an 11-digit format to provide a consistent "5-4-2" hyphenated representation of the NDC for certain data processing applications.

When third-party billing of prescription drug claims became commonplace, a business case was made for formatting the 10-digit NDC into an equivalent 11-digit format so the NDC could be represented in a consistent "5-4-2" human-readable manner. To facilitate this third-party billing, first on paper and then by electronic means, the National Council for Prescription Drug Programs (NCPDP) developed a standard in which the manufacturer/labeler segment is always represented by five digits, the product segment by four digits and the packaging segment by two digits.

Below are examples of the three FDA-prescribed NDC formats and the methods for reformatting them into 11 digits for use in accordance with NCPDP-based applications by the placement of a zero in the proper position. In a "4-4-2" format, the zero is placed in the first position of the leading segment. In a "5-3-2" format, the zero is placed in the first position of the middle (second) segment (i.e., the sixth position of the unhyphenated code). Finally, in a "5-4-1" format, the zero is placed in the first position of the last (third) segment (i.e., the 10th position of the unhyphenated code). In all three cases the resulting format is "5-4-2."

NDC number listed with and recognized by FDA 10-digit format	NCPDP "5-4-2" 11-digit format
4-4-2 (1234–5678-99)	01234-5678-99
5-3-2 (12345-678-99)	12345-0678-99
5-4-1 (12345-6789-9)	12345-6789-09

Figure 1

The NCPDP representation of the FDA-prescribed 10-digit NDC is not the same as the NDC. Only the FDA-prescribed 10-digit NDC, without the hyphens, can be encoded in GS1 or HIBCC data formats in accordance with the FDA bar code rule and be included within the SNI mandated by the DSCSA36 Furthermore, it is not physically possible to embed an 11-digit number within the rules established for embedding the NDC within the GS1 GTIN data structure.

Similarly, labelers/manufacturers may use an internally generated list, order or product numbers that are non-specific to a trade package or SKU. Instead, these numbers should be the full 10-digit NDC numbers used for EDI.

GUIDELINE RECOMMENDATION

These guidelines further recommend that the NDC, in its three-segment format, be presented on the product label.

36. 21 C.F.R. § 201.25 (bar code rule); § 581(20), 21 U.S.C. § 360eee(20) (definition of SNI).

GUIDELINE RECOMMENDATION

These guidelines continue to recommend that manufacturers and labelers rely on the unique GS1 GTIN identifier associated with each drug at each packaging level in their catalogs and on price lists. In the following section, "The Product Identifier," the guidelines address GTIN assignment in more detail, as well as how to encode that information into a 2D Data Matrix bar code that complies with the DSCSA's requirements.

UPCs, NDCs and GS1 Company Prefixes for Pharmaceuticals

The Global Trade Item Number (GTIN), previously known as the UPC numbering system, is administered by GS1. There are four formats of GTIN: GTIN-8, GTIN-12, GTIN-13, and GTIN-14. These are discussed in other sections (when relevant to pharmaceutical bar codes). Refer to the GS1 General Specifications for more details.

The GTIN-12 is a 12-digit, fixed length identifier used to unique identify products and services that can encode the NDC and is used in the UPC-A symbology and other barcodes, such as the GS1 DataMatrix and GS1-128. The UPC-A symbology is a proven and reliable data carrier and best meets the needs of the pharmaceutical supply chain for SKU-level packaging. It should be noted that when discussing "UPC" there is a difference between the UPC-A symbology (the bars and spaces) and the UPC numbering scheme or GTIN-12 data structure, which often is printed in a human-readable form that may include hyphens (especially when it encodes the NDC). Hyphens, however, are neither part of the data structure, nor are they encoded in the bar code.

Embedding the NDC within the GTIN-12 data structure and represented in the UPC bar code symbol has become the de facto standard practice in the U.S. for pharmaceutical products.

Since the inception of UPC numbering in the early 1970s, a provision was made to allow every pharmaceutical and health-related item manufacturer/labeler to apply to GS1 US and obtain the "Company Prefix that coincides with their FDA labeler code. Since that time, the 10-digit NDC has been embedded within the 12-digit UPC-A symbol, with the NDC preceded by the number "3" and followed by a modulo-10 check digit. The check digit is calculated on all 11 leading digits, including the leading prefix "3."

Your company must obtain a GS1 Company Prefix through a GS1 Member Organization (such as GS1 US) to guarantee that the prefix is authentic. This will ensure that your GS1 bar codes are globally unique and that the data contained in them can be authenticated through the Global GS1 Electronic Party Information Registry (GEPIR), Global Data Synchronization Network (GDSN; for example, GS1 US Data Hub) and EPC Information Services (EPCIS). The direct link to apply for a GS1 Company Prefix in the U.S. is: https://my.gs1us.org/product/1024/gs1-company-prefix?_ga.

GTIN-12 in UPC-A barcode

Figure 2

THE PRODUCT IDENTIFIER

As discussed previously, the DSCSA required that by November 27, 2018,[37] manufacturers and repackagers must affix or imprint a "product identifier" to each package and homogeneous case of a product intended to be introduced in a transaction into commerce.[38] A "package"[39] is the smallest individual saleable unit of product — the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

Figure 3

This product identifier must be in a standardized graphic in both a human-readable format **and** on a machine-readable data carrier in a 2D Data Matrix bar code affixed to, or imprinted upon, a package[40] and the product identifier must conform to the standards developed by a widely recognized international standards development organization.[41] The product identifier must also be affixed to or imprinted on each homogeneous case in **either** a linear or 2D Data Matrix bar code.[42]

These guidelines address how to create a DSCSA-compliant product identifier, using GS1 standards and encode it in a 2D Data Matrix bar code using the correct GS1. Application Identifiers or AIs. The AI, which precedes each data element, is an all-numeric "flag" designated by GS1 to identify each of the more than 180 distinct data elements in use throughout the global GS1 system. AIs are shown in the human-readable text within parentheses. In accordance with GS1 specifications, the parentheses are not encoded in the bar code.

As discussed previously, in June 2021 the FDA published the Product Identifier Final Guidance. In that final guidance, FDA stated that it does not "recommend" using the GTIN in place of the NDC in the human-readable portion of the product identifier. FDA stated it would not object to the GTIN being included in the human-readable portion of the product identifier so long as the NDC was also present. FDA also stated that it understood companies were using the GTIN to encode the NDC into the 2D Data Matrix and that "FDA views this practice as satisfying the requirement for a machine-readable NDC in product identifiers."[43]

FDA's position notwithstanding, it is the strong recommendation of these guidelines that including the GTIN in the human-readable portion of the product identifier is necessary to uniquely serialize the product and to assure its compliance with international GS1 standards — both requirements of the DSCSA. **Though the Product Identifier Final Guidance would seem to permit the NDC alone in the human-readable portion of the product identifier, these guidelines do not recommend presentation of the NDC alone.**

37. As discussed previously, this requirement to affix or imprint the product identifier to each package and homogeneous case of a product intended to be introduced in a transaction into commerce went into effect for manufacturers on November 27, 2017, though the agency granted a year of enforcement discretion. The deadline for repackagers remained November 27, 2018. As of that date, all covered products packaged by manufacturers or repackagers must bear a product identifier.

38. § 582(b)(2)(A), § 21 U.S.C. § 360eee-1(b)(2)(A).

39. § 581(11), § 21 U.S.C. § 360eee(11).

40. § 581(14), 21 U.S.C. § 360eee(14).

41. § 582(a)(9)(A)(i), 21 U.S.C. § 360eee-1(a)(9)(A)(i). Previous editions of these guidelines emphasized barcoding at the SKU-level package size. In this update, the guidelines align with the DSCSA's definition of "package," that is, the smallest individual saleable unit of a product that the manufacturer or repackager intended to sell to a dispenser [§ 581(11), § 21 U.S.C. § 360eee(11)].

42. § 581(14), 21 U.S.C. § 360eee(14).

43. § 582(a)(9)(A)(ii), 21 U.S.C. § 360eee-1(a)(9)(A)(ii).

Per the Product Identifier Final Guidance, some companies may elect to include both the NDC and the GTIN in the human readable portion of the product identifier. Note that the NDC will not be encoded in the machine-readable product identifier. If companies choose to include both the NDC and the GTIN in the human-readable portion, the recommended order for printing the human readable is NDC, GTIN, Serial Number, Lot, Expiry. Space constraints, other packaging challenges or business decisions will impact whether a company chooses to include both the NDC and the GTIN along with the human readable interpretation or near the bar code. If a company elects to not include the NDC in the human readable portion of the product identifier, the NDC, in its three-segment format, should appear elsewhere on the product label.

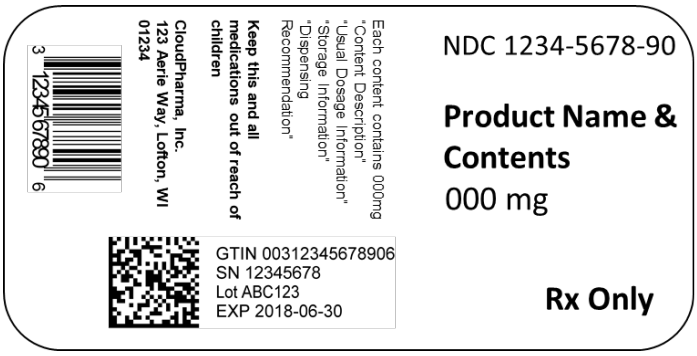


Figure 4A

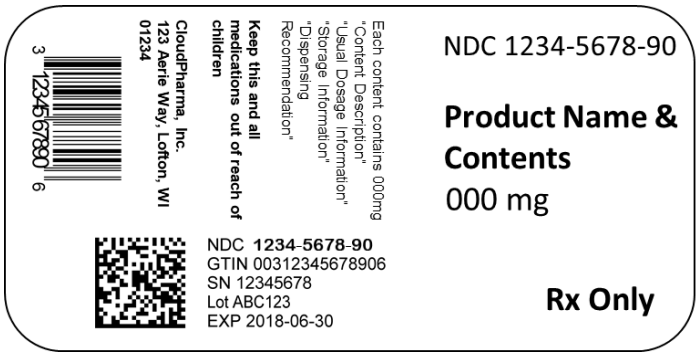


Figure 4B

GUIDELINE RECOMMENDATION

These guidelines recommend encoding the product identifier as below using the GS1 DataMatrix data carrier:

GTIN (with the **NDC** embedded) **AI(01) + 14-digit GTIN**, unit-level serial number [AI(21) + 1-20-digit serial number], lot number [AI(10) + 1-20-digit alphanumeric lot number] and expiration date [AI(17) + 6-digit date in YYMMDD format] using the GS1 DataMatrix data carrier.

A valid day (NOT "00") should be used in the AI(17) six-digit date so that the expiration date encoded exactly matches electronic data passed between trading partners. Additionally serial numbers and lot numbers should not have leading zeros. Information and summaries of these GS1 AIs [AI(01), AI(21), AI(17), AI(10)] are available in the GS1 General Specification.

PRODUCT IDENTIFIER COMPONENTS

The GTIN

The Global Trade Item Number (GTIN) is the GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix (obtained from GS1 and discussed above in the previous section, "Configuring the NDC in Bar Codes"), an item reference and a check digit. These guidelines continue to recommend that manufacturers and labelers identify their drug packages (i.e., individual saleable units)[44] by GTIN using the standardized GS1 system bar code format that incorporates the product's NDC. The support for this approach is found in the DSCSA's requirement that the product identifier must conform to the standards of an international, standards setting organization and in the SNI Final Guidance. In accordance with GS1 global standards and the SNI Final Guidance, the NDC can be represented in a GTIN, to which a unique serial number can be added. Manufacturers and labelers have been complying with the DSCSA's serialization requirements using this process and are affixing product identifiers that include the GS1 GTIN data structure (or code) to carry the NDC on drug packages.

GTINS:

- Are assigned by the owner of the NDC.
- Uniquely identify a product at each packaging level at which there is a need to retrieve predefined information. A separate, unique GTIN is required when any of the predefined characteristics of an item are different in any way that is relevant to the trading process. This is particularly critical for any changes in pack/case quantity — once a GTIN is assigned to a particular product pack or case, any change in the number of trade items in the pack or case requires assignment of a new GTIN.
- Can be serialized to uniquely identify the product.
- Are used for any item that may be priced, ordered or invoiced at any point in the supply chain.[45]
- Unlike the NDC, are valid and unique globally and comply with an international standard.
- Where manufacturers or repackagers have multiple packs of the same product for different markets (i.e., countries), it may be necessary to allocate a new GTIN depending upon differences in packaging or labeling for different markets.
- Although selection of the "indicator digit" in the allocation of GTINs is up to the company, indicator digits for levels of packaging above the lowest saleable trade item should be restricted to numbers between "1" and "8." Indicator digit "9" is restricted to variable measure trade items and is not applicable to drug products as related to the DSCSA regulations. The lowest-level trade item is normally represented as a GTIN-12 for display as a linear barcode in UPC-A format and, when encoded for DSCSA product identifier purposes, the GTIN-12 will be encoded into a 14-digit format by adding leading zeros. This lowest level of packaging must not be given an indicator digit (other than leading zeros), because GS1 rules will not permit two different GTINs on the same package. For more guidance on this topic, see the GS1 Guidance for Pharmaceutical Products Marked with Both U.P.C-A and GS1 DataMatrix.[46]

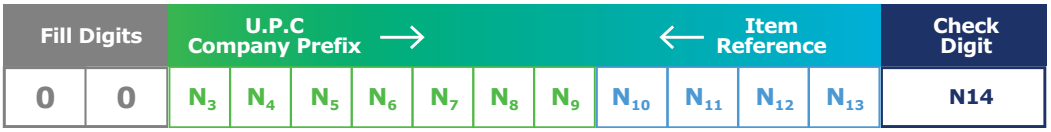
Figure 5

44. https://www.gs1.org/1/gtinrules/en/healthcare
45. *See* definition of "package," § 581(11), 21 U.S.C. § 360eee(11).
46. https://www.gs1.org/sites/default/files/docs/barcodes/GS1_GTIN_Management_Standard.pdf.

Converting the GTIN structure to a storable/sharable format

It is recommended that GTINs be stored in databases and applications as 14-digits. If necessary, when sharing or storing a GTIN-8, GTIN-12, or GTIN-13, you can accomplish this by right justifying and then zero-filling left to create a 14-digit format.

- GTIN-12 in a 14-digit format — for certain GS1 barcodes, sharing with trading partners (for database storage), and U.S. FDA GUDID



The FDA does not assign four-digit drug labeler codes in the range of 1000 through 9999. This prevents NDC numbers (without the hyphens) from being repeated between two different companies. Subsequently, any GTINs allocated based on NDC numbers listed with the FDA will not be repeated between two different companies.

As discussed in the previous section, the GS1 "Company Prefix" is assigned by GS1; in the U.S., the UPC Company Prefix is the company's FDA-assigned labeler code preceded by the number "3." The use of this leading prefix of "3" is specifically reserved for drug products using an NDC format and other healthcare products using a National Health Related Item Code (NHRIC) format.

With the UPC Prefix check digit:

NDC Format	GS1-US	Labeler	Product	SKU /Trade/ Package	Mod-10 Check
5-4-1	3	NNNNN	NNNN	N	N
4-4-2	3	NNNN	NNNN	NN	N
5-3-2	3	NNNNN	NNN	NN	N

Figure 6

From the NDC examples:

5-4-1 Format: NDC 22222-8395-5

4-4-2 Format: NDC 0001-4096-60

5-3-2 Format: NDC 11111-569-73

Where the NDCs are embedded and expressed in a GTIN and linear bar code:

Figure 7

GS1 rules outline that Human-Readable Interpretation (HRI) of the bar code should reflect what is encoded, therefore, using "N" or hyphens in the HRI would violate that rule. However, many UPC bar code software programs will automatically insert the "N" into the outputted UPC file if the UPC begins with a "3" as the default setting. This guidance recommends that the "N" and hyphens in the HRI be omitted, understanding that the use of "N" and hyphens in this context is historical and may be considered of value for continued use knowing that this violates GS1 HRI rules. The following is an example of properly constructed GTIN that incorporates the product's NDC:

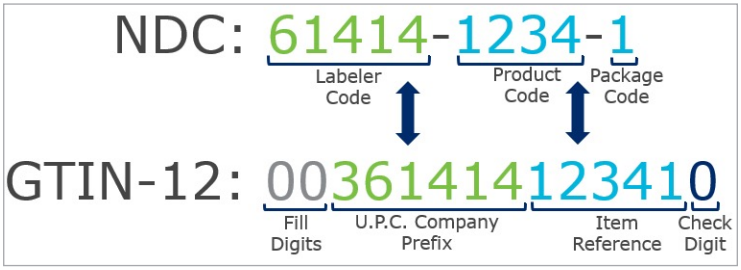


Figure 8

For further information on how to construct a GTIN, assign GTINs to products, and understand the circumstances that require a new GTIN, see the GS1 GTIN Allocation rules. The GS1 standards have evolved over more than 40 years and are now strictly codified for global use in the GS1 General Specifications. These documents are available at the GS1 website.

Also, as discussed in the section outlining FDA's bar coding requirements, a new FDA drug listing rule went into effect on November 29, 2016. This new rule amended when changes to a product require the manufacturer or labeler to assign a new NDC number.[47] A new NDC number will trigger changing the GTIN as well.

47. The *Federal Register* notice publishing the final rule is available at https://www.federalregister.gov/documents/2016/08/31/2016-20471/requirements-for-foreign-and-domestic-establishment-registration-and-listing-for-human-drugs. The rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017)

Serializing the GTIN

To comply with the DSCSA, the product identifier must include the SNI, which uniquely identifies each product package[48] (or homogeneous case.[49] That SNI comprises the NDC (recommended here to be embedded within the product's GTIN) plus a unique alphanumeric serial number of up to 20 characters.[50] As discussed in this section, the FDA provided advice on how to create a unique SNI in the SNI Final Guidance. In the SNI Final Guidance, FDA recognized (and these guidelines recommend) that an NDC be presented within a GTIN AI(01) followed by a 20-character unique identification in GS1 AI(21) format to create a serialized GTIN (sGTIN). FDA now states in the Product Identifier Final Guidance that it is acceptable to present the NDC within the GTIN in the machine-readable 2D bar code the DSCSA requires and that it may be presented optionally in the human-readable portion of the product identifier.[51]

NDC 1234567890
GTIN 00312345678906
SN 12345678
Lot ABC123
EXP 2018-06-30

Figure 9A

GTIN 00312345678906
SN 12345678
Lot ABC123
EXP 2018-06-30

Figure 9B

To continue the example from above to build a product identifier:

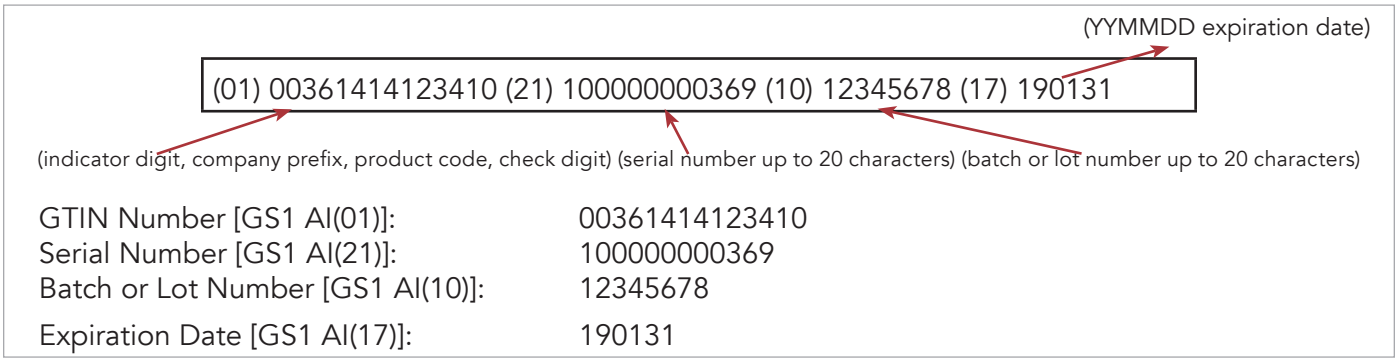


Figure 10

It is best practice to avoid issuing serial numbers with leading zeros to ensure interoperability with 96-bit EPC/RFID tags, which cannot accommodate leading zeros in serial numbers. Leading zeros should never be added or removed from serial numbers, and care should be taken that applications are not automatically altering leading zeros. This includes, but not limited to, the possibility of erroneous and unexpected truncation of leading zeros because of numeric field formatting. Where possible, it is best to configure systems to capture and store serial numbers as a text field to avoid these issues.

Serial number format is also addressed in the Product Identifier Final Guidance. FDA has recommended the following abbreviations for "Serial Number" in the HRI:

➢ Serial ➢ Serial No. ➢ Ser. No.	➢ S/N ➢ SN, *while not included in the FDA guidance, is also commonly used by manufacturers.*

48. A "package" means 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" [§ 581(11)(A), 21 U.S.C. § 360eee(11)(A)].

49. A "homogeneous case" means a sealed case containing only product that has a single [NDC] number belonging to a single lot" [§ 581(7), 21 U.S.C. § 360eee(7)].

50. § 581(20), 21 U.S.C. § 360eee(20).

51. SNI Final Guidance at page 7.

Lot Number

The DSCSA requires inclusion of the product's lot number in the product identifier. These guidelines recommend the GS1 AI(10) with 1 to 20 alphanumeric characters representing the batch or lot number. The best practice is to avoid leading zeros and start instead with an alpha character or a non-zero digit. Companies have run into challenges when the lot is not configured as a text field. When configured as a numeric field, in some instances, leading zeros can be dropped leading to validation concerns.

In the Product Identifier Final Guidance,[52] FDA has recommended the following abbreviations for "Lot Number" in the HRI:

➢ Lot	➢ Lot No.	➢ LOT

GUIDELINE RECOMMENDATION

Recommendation on Using Special Characters in Lot Numbers:

Special characters included in bar codes can cause challenges to systems. Verification failures have occurred because of special characters used in manufacturer's lot and serial numbers. The GS1 General Specification permits specific special characters in alphanumeric fields. When analyzing GS1's 2020 Barcode Assessment data, the most frequently used special characters are the dash, period and forward slash and they are predominantly included in the lot number.

The HDA Task Force recommends that the use of the following four characters be avoided to the extent possible as they may cause challenges to interoperability, readability and traceability if systems have not been updated to support special characters:

"	Quotation mark	.	Full stop
-	Hyphen/Minus	_	Low line

It is important that service providers update their systems to support all special characters.

A manufacturer or repackager that finds it necessary to use or continue to use special characters will impose fewer burdens upon other trading partners and ease data flow if it follows GS1 standards for encoding special characters.

52. Product Identifier Final Guidance at page 9.

Expiration Date

The DSCSA requires inclusion of the product's expiration date in the product identifier. These guidelines recommend the GS1 AI(17) + six-digit date in a YYMMDD format.

The AI for expiration date, AI(17), requires the "YYMMDD" (Year, Year, Month, Month, Day, Day) format; no other expiration date format is supported or allowed in the GS1 system. Currently, some suppliers do not designate a day of the month as part of their expiration date in non-HRI text. In this case "00" is used in the GS1 system as a place holder for the "DD" date segment when no day of the month is specified (the resultant string shall be interpreted as the last day of the month, including any adjustment for leap years). Note that as of January 1, 2025 it will no longer be permissible to use "00" in the GS1 system for healthcare items.

The HDA Bar Code Task Force does not support the use of "00" as the day of the month and recommends using a specific day of the month such as "31" so that the expiration date encoded exactly matches electronic data passed between trading partners. For example, a product with an 01/2019 (or JAN 2019) expiration date would be presented as: 190131 (omission of day of month in non-HRI text shall be interpreted as the last day of the month — only the last day of the month should be encoded in the data carrier if the day is omitted in the non-HRI text depicting expiration).The HDA Bar Code Task Force does, however, recognize that a period of transition is now in underway, and some systems may still use "00" as the day of the month.

In the non-HRI text depicting the expiration there are now suggestions from USP and FDA. The goal of these formats is so that they can be more readily understood by those purchasing and using products. A four-digit year must always be used.

GUIDELINE RECOMMENDATION

Leading zeros should be avoided in serial numbers. Additionally, it is best to configure systems to capture and store serial numbers as a text field to avoid issues with systems truncating leading zeros. The HDA Bar Code Task Force does not support the use of "00" as day of the month, as outlined in the new formatting rules.

In the Product Identifier Final Guidance,[53] FDA addressed its preferred presentation of the expiration date.

> The expiration date may contain letters or numbers as determined by the manufacturer or repackager of the product. FDA recommends that the human-readable expiration date on the drug package label include a year, month and day in YYYY-MM-DD format (e.g., 2021-01-01) if using only numerical characters (noting that day should not be expressed as "00"); or in YYYY-MMM-DD (e.g., 2021-JAN-01) if using alphabetical characters to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, expressed as YYYY-MM (e.g., 2021-01) if using only numerical characters or YYYY-MMM (e.g., 2021-JAN) if using alphabetical characters to represent the month. FDA recommends using a hyphen or forward slash to separate the portions of the expiration date
>
> In situations where the expiration date includes only a year and month due to space limitations, FDA considers the drug's actual expiration date to be the last calendar day of the month that is included in the human-readable expiration date on the drug package label. For example, a human-readable expiration date of 2021-07 (or 2021-JUL) would be interpreted by FDA to mean that the drug expires on July 31, 2021.

53. Product Identifier Final Guidance at pages 9-10.

The GSI AI(17) standard requires the "YYMMDD" (Year, Year, Month, Month, Day, Day) format; no other expiration date format is supported or allowed in the GS1 system.

Currently USP requires that an expiration date be "read by an ordinary individual under customary conditions of purchase and use. The expiration date shall be prominently displayed in high contrast to the background, or it shall be sharply embossed and easily understood (e.g., "EXP 6/13," "Exp. June 13," or "Expires 6/2013")."[54] **It is important to note that the USP formats noted below take effect on September 1, 2023.[55] During this transition period, other readily understandable formats may be used.**

Suggested USP and FDA Abbreviations

Per USP, the term "expiration date" may be abbreviated in a way that allows for easy comprehension (e.g., EXP, Exp Date, Expiry). However, it must be printed or sharply embossed or debossed to be clear to the user. In the Product Identifier Final Guidance, FDA recommends using one of the following abbreviations for expiration date:

➢ EXP. ➢ EXP ➢ EXPIRY.	➢ EXP DATE ➢ Exp. Date.[56]

Suggested USP and FDA Formats

When all numeric dates are used, they must be formatted using the year, the month, and, if applicable the day, separated by hyphens or forward slashes in one of the following formats:

YYYY-MM-DD (e.g., 2019-06-30, 2019/06/30) *preferred FDA format
YYYY-MM (e.g. 2019-06, 2019/06) *FDA okay with this format if there are space limitations

The FDA recommends[57] that the expiration date in the human-readable portion of the product identifier appear as:

YYYY-MMM-DD (ex., 2021-JAN-01) if using alphabetical characters to represent the month, or
YYYY-MM-DD (ex., 2021-01-01) if using only numerical characters.

When alphanumeric dates are used, FDA recommends three letters to display the month. For example,

YYYY-MMM-DD (e.g. 2019-JUN-30, 2019/JUN/30)

FDA permits an abbreviation of YYYY-MM (if numerical) and YYYY-MMM (if alphanumerical) if there are space limitations.[58]

In situations where the expiration date includes only a year and month due to space limitations, FDA considers the drug's actual expiration date to be the last calendar day of the month that is included in the human-readable expiration date on the drug package label.[59] If there is insufficient space on the primary container for the full expiration date format, then USP recommends using the all-numeric YYYY_MM or the alphanumeric format YYYYMMM (without hyphen or forward slash to accommodate

54. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-7-labeling-rb-notice-20190830.pdf.
55. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-7-ira-20200731.pdf.
56. Product Identifier Final Guidance at page 9.
57. Product Identifier Final Guidance at page 10.
58. Product Identifier Final Guidance at page 10.
59. § 581(14), 21 U.S.C. § 360eee(14).

space constraints). In these instances, it is acceptable to omit "expiration date" or "exp" text, but all other packaging including but not limited to a carton, tray or overwrap must have the full expiration date as described above.

GS1 General Specifications clearly differentiate between HRI and non-HRI text. Under this GS1 standard, HRI follows strict rules based on data encoded within the data carrier. HRI is the information that appears below, beside or above a bar code and represents the exact same information that is carried in the bar code or tag. Non-HRI text is all other text on the package, label or item.

The guidelines make specific recommendations on labeling for HRI and non-HRI text. HDA's guidelines recommend that the year always be represented in its complete "CCYY" (Century, Century, Year, Year) four-digit format when represented as non-HRI text.

Expiration Date	Non-HRI Text	YYMMDD Encodation
January 31, 2021	JAN 31, 2021	210131
January 31, 2021	31 JAN 2021	210131
December 2021	DEC 2021	211231
December 2021	12/2021	211231
December 15, 2021	2021/12/15 or 2021 DEC 15	211215
December 31, 2021 (space constraint)	2021DEC or 2021-12	211231

Figure 11

In both the first and second formats, the human-readable expiration date is transcribed into an equivalent bar code data format, as illustrated by the examples in the preceding table. Although the human-readable and the encoded bar code formats are not identical, they are exactly equivalent and the information conveyed is identical.

GUIDELINE RECOMMENDATION

The non-HRI text for year should always be represented in its complete "CCYY" four-digit format. Non-HRI text may omit day of the month only if the encoded data depicts the last day of the month.

It is generally preferred in pharmaceutical trade that text data titles (i.e., "GTIN," "SN," "LOT," "EXP") be used to further aid in human interpretation in the HRI data. GS1 allows for combining HRI with non-HRI text where it is desired to deviate from standard GS1 HRI rules; whenever the data part of text matches that which would appear according to GS1 HRI rules, GS1 expects that the AI with parenthesis be included in the data title.

HDA guidelines recommend a deviation from GS1 rules and recommendations, and propose the use of non-HRI text with data titles and no AIs. The HDA Bar Code Task Force believes this will reduce confusion and improve interpretation, especially for downstream trading partners who may be unfamiliar with GS1 Application Identifiers.

Figure 12

The graphic above represents examples of HRI and non-HRI text as would be represented on a unit- of-sale label. Where the GS1 preferred HRI is technically compliant with GS1 standards (use of AIs within parentheses), these Guidelines recommend the use of non-HRI text with data titles and no AIs.

Some companies prefer to preprint the text describing GTIN on the label artwork. This can free up space on the label in the area allocated for the Data Matrix and variable print. See the following example:

Figure 13

Recommendation to Cease Using AI(22) and AI(30)

AI(22), which can combine quantity, expiration date, lot number and a link character into one compact code, has been widely (and sometimes incorrectly) used. With the publication of its GS1 General Specifications, Issue 10 (January 2010), GS1 formally announced the withdrawal of AI(22), effective January 1, 2013. The HDA guidelines, similarly, do not recommend continued use of the AI(22).

These guidelines recommend eliminating all uses of AI(22), with the affected package labels revised to use AI(17), AI(10) and AI(30), as appropriate. Inclusion in the GS1 DataMatrix symbol of the explicit case quantity represented by AI(30) is not in accordance with GS1 General Specifications and GS1 standards no longer permit it. Additionally, as discussed, the DSCSA requires encoding the product identifier into a 2D Data Matrix bar code and quantity is not a required component of the product identifier.

In accordance with the DSCSA, and as discussed previously, HDA's guidelines recommend encoding NDC [AI(01) + 14-digit GTIN], serial number [AI(21) + 1-20-digit serial number], expiration date [AI(17) + 6-digit date in YYMMDD format] and lot number [AI(10) + 1-20-digit alphanumeric lot number]. As noted in the section on bar codes for cases, a case quantity could be expressed as AI(30) + 1-8-digit case quantity in a GS1-128 bar code and in the GS1 DataMatrix. However, inclusion of a case quantity in the GS1 DataMatrix symbol represented by AI(30) is not in accordance with GS1 General Specifications and GS1 standards no longer permit it. During a transition period where the historical GS1-128 primary and secondary linear bar code symbols are still in use, the inclusion of case quantity using AI(30) in the secondary linear bar code will continue to be the recommended practice. However, the HDA Bar Code Task Force is considering the discontinuation of a recommendation of the use of AI(30) at a future date. A transition period will allow adoption of alternate technologies.

GUIDELINE RECOMMENDATION

If employing AI(30) the guidelines recommend encoding the quantity of trade items contained in the case in a secondary linear bar code and not in the GS1 DataMatrix. Inclusion of the explicit case quantity in the GS1 DataMatrix symbol represented by AI(30) is not in accordance with GS1 General Specifications, GS1 standards no longer permit it, and quantity is not a component of the DSCSA product identifier. However, during a transition period where the historical GS1-128 primary and secondary linear bar code symbols are still in use, the inclusion of case quantity using AI(30) in the secondary linear bar code will continue to be an accepted practice.

TWO-DIMENSIONAL (2D) BAR CODE

The DSCSA requires that the product identifier be presented as "a standardized graphic … in both a human-readable format and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization."[60] That machine-readable portion of the product identifier:

- Shall be included in a 2D Data Matrix bar code when affixed to, or imprinted upon, a package; and,
- Shall be included in a linear or 2D Data Matrix bar code when affixed to, or imprinted upon, a homogeneous case.[61]

These guidelines recommend that the product identifier be encoded in a GS1 DataMatrix. The DSCSA requires that the product identifier conform to the standards of a widely recognized international standards development organization; GS1 standards are the only such standard that exist to identify and transmit product information.

Originally developed as a proprietary symbology with various capacities and properties (versions ECC80-ECC140), an advanced version, Data Matrix ECC200, was developed with the support of the Association for Automatic Identification and Mobility (AIM) and introduced into the public domain (hereafter known as ISO/IEC Data Matrix). Data Matrix is described and recommended here for converting the human-readable product identifier into the 2D Data Matrix the DSCSA requires. The Data Matrix permits direct-part marking (such as etching, peening or stamping a symbol into metal) and has an error-correction feature, which can allow a symbol to be read even if it is damaged (up to 30 percent, depending on where the damage occurs).

These features were factors in the 2004 GS1 adoption of Data Matrix as an allowable symbology within the global GS1 system. The ISO/IEC Data Matrix is the only Data Matrix symbology GS1 permits.

It includes the special character FNC1 in the first position, to create what is referred to as the GS1 DataMatrix.

ISO/IEC Data Matrix symbols have other beneficial features. Most significantly, they have a high data-carrying capacity in a very small "footprint." For the pharmaceutical supply chain, the GS1 DataMatrix version of the symbology is capable of encoding primary item identification (NDC embedded within GTIN), as well as other DSCSA-required information — unique serial number, expiration date and lot number in a substantially smaller area than a linear symbol. The GS1 DataMatrix and Electronic Product Code (EPC) RFID tags can encode the same data so the same information can be captured when both data carrier methods are required. The DSCSA specifies a 2D Data Matrix for the encoding of the product identifier, not RFID.[62] These Guidelines, therefore, do not provide recommendations for RFID use as it is not compliant with the DSCSA.

In an ISO/IEC Data Matrix, the outer perimeter of the code is used to establish the bounds and size of the matrix. The left and bottom sides (called the finder pattern) are solid; the right and top sides (called the timing or clock track) are an alternating pattern of black and white cells. Damage to the finder pattern or clock track significantly reduces the ability of a scanner to read the symbol.

60. § 582(a)(9)(A), 21 U.S.C. § 360eee-1(a)(9)(A).

61. § 582(a)(9)(A), 21 U.S.C. § 360eee-1(a)(9)(A).

62. Product Identifier Final Guidance at page 11.

Using the grid pattern established from the finder pattern and the clock track, a Data Matrix scanner determines if an area in the center on an individual cell of the grid is black or white. For example, a 20x20 matrix has 400 cells. When attempting to decode or read a Data Matrix symbol, only the center of the cell is considered, whereas with a linear bar code it is the placement of the edges and the width of the bars that is meaningful.

Because of this design, Data Matrix is generally much easier to print and read than a linear code. Edge quality is much less important since the imaging scanner is only looking at the center of the cell to see if it is light or dark. The symbol can be printed via laser engraving, laser ablation, inkjet, hot foil stamping and thermal transfer as well as by traditional wet ink processes, marking another key benefit of this system. In many industries (such as automobiles and computers) an embossed or dot peened Data Matrix code is used to encode part numbers and/or unique serial numbers.

ISO/IEC Data Matrix can be printed in either a square or a rectangular format, although square is more common, and readers can generally read either format equally well. The symbols below are reproduced at actual size.

Figure 14

Above: ISO/IEC Data Matrix symbols encoding "Healthcare Distribution Alliance" at a cell size ("X-dimension") of 30 mils.

For additional information on the structure and how to encode a GS1 DataMatrix, see the GS1 DataMatrix Guideline: Overview and technical introduction to the use of GS1 DataMatrix at https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf.

GUIDELINE RECOMMENDATION

The GS1 DataMatrix should include the GTIN AI(01) + the serial number AI(21) + the lot number AI(10) + the expiration date AI(17) to create the DSCSA-compliant product identifier encoded in a 2D Data Matrix bar code with appropriate encoding using Function 1 and Group Separators so the elements can be parsed correctly when scanned.

The encoded data could appear in various orders. The order below is only one example. Importantly, items should be properly encoded:

> <FNC1> + AI(01) + GTIN + AI(21) + Serial Number + <FNC1> + AI(10) + Lot Number + <FNC1>+ AI(17) + Expiration Date

While FDA specifies in the Product Identifier Final Guidance that the NDC should be included in the human-readable text, the agency "also understands that companies utilize the GTIN to encode the NDC into the 2D Data Matrix barcode." The Product Identifier Final Guidance states that "FDA views this practice as satisfying the requirement for a machine-readable NDC in product identifiers."[63]

63. § 582(a)(9)(A)(ii), 21 U.S.C. § 360eee-1(a)(9)(A)(ii).

The first FNC1 (or "Function 1") is a special bar code character that must be encoded in the first character position in a GS1-128 or GS1 DataMatrix bar code to indicate that this is a GS1 bar code. (See the GS1 General Specifications for complete details about GS1 data structures and encoding FNC1 in GS1-128 and GS1 DataMatrix.) When FNC1 is encoded as the character Group Separator, and often denoted by the convention "<GS>" or "GS," is used to terminate the variable length serial number and lot number prior to starting the next AI.

When an AI appears last in an element string, it is unnecessary to terminate the last field with a Group Separator even if a variable- length field. The parentheses are not encoded in the bar code — they are only shown in a human-readable format. This sequence of data elements deviates from the recommendation in the GS1 General Specifications to encode all fixed-length data elements before variable-length data elements. However, given the practical limits on the length of scanned data in many current automatic data capture systems — and the priority to capture the SNI (GTIN/NDC + unique serial number), potential problems will be avoided if the GTIN/NDC + unique serial number combination always is listed first in the encoded data. In virtually every case, the resulting GS1 DataMatrix symbol will be no larger than it otherwise would be and the essential GTIN/NDC + unique serial number data always will be captured.

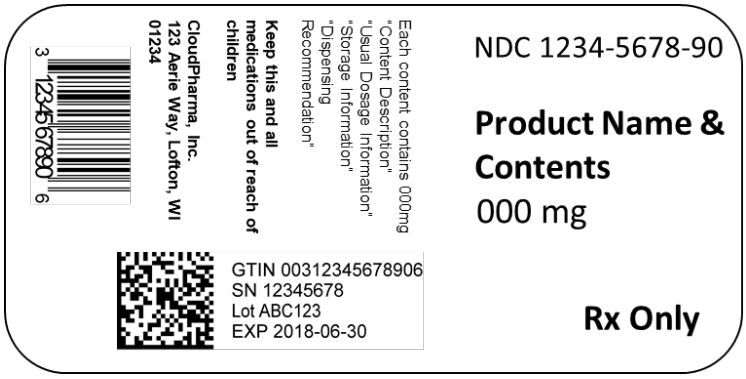


Figure 15

A scan of the GS1 DataMatrix symbol above yields the following data string without the parentheses:

]d2(01)00312345678906(21)12345678<FNC1>(10)ABC123(17)180630

Note: In the example above, the symbology identifier,]d2, and group separator, <FNC1>, may not appear at all or appear differently depending on the scanning device used and how it has been set up.

Below is an example of same label with NDC added to the human-readable text:

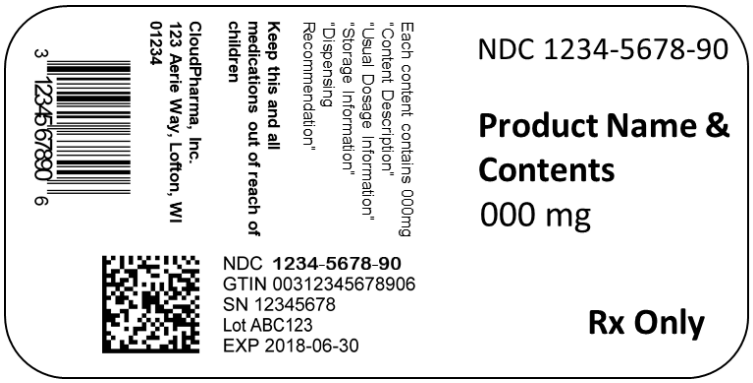


Figure 16

This example lists multiple data carriers on saleable units/trade items.

Multiple Data Carriers on a Product: Use Identical Serial Numbers

Whenever serial numbers are affixed to saleable units or trade items using two or more data carriers per item (including two distinct bar code data carriers), the serial number encoded in all data carriers must be identical. For example, if a manufacturer applies the minimally required GS1-128 linear bar codes and/or a complimentary GS1 DataMatrix bar code as called for in these guidelines and/or an RFID tag to a saleable package of drugs, the GTIN + Serial Number encoded in the GS1 DataMatrix symbol and/or the RFID tag must be identical to the GTIN + Serial Number encoded in the GS1 bar code. If RFID tags are used, which is not required for DSCSA and would be a purely business decision, each saleable unit should be uniquely identified by a single EPC that has an identical serial number (strictly functionally equivalent) to the serial number in the GS1 bar code. This prevents ambiguity and confusion when the trade items are read.

Multiple Bar Codes: Maximize Spacing and Use Quiet Zones

When designing a unit-package label (or carton) including multiple bar codes (i.e., a UPC/linear barcode encoding the NDC, a GS1 DataMatrix for GTIN + Serial Number + Expiration Date + Lot, or a component control bar code, etc.), care must be taken to maximize the separation between the various symbols to eliminate — or at least minimize — the likelihood of the reader/imager picking up more than one symbol at a time. This will render downstream business processes more efficient.

If bar codes lie too close together, scanners will pick up the first bar code they read, rather than the intended bar code. This results in multiple scans and less efficient processes. Quiet zones, as specified in the GS1 General Specifications, should be followed. Where possible, putting bar codes on different sides of a bottle or the opposite end of a flat label is optimal.

Using QR Codes on Labels for COVID-19 Vaccines and Other Therapeutic Products

During the COVID-19 pandemic, vaccines and other therapeutics under FDA Emergency Use Authorization with limited stability data often have included a QR code on the product. This 2D code is separate from the serialized 2D Data Matrix bar code and generally used to provide a fact sheet and additional information on extended expiry dating when applicable. See the example below. Note that other best practices such as spacing and quiet zones should continue to be maintained.

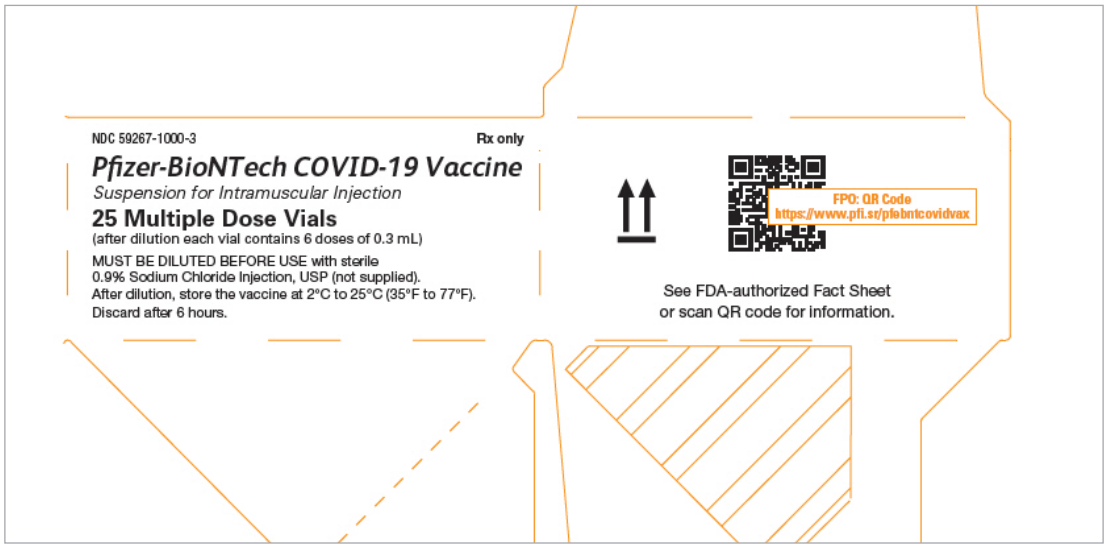


Figure 17

Electronic Product Code Information Services (EPCIS)

The EPC Information Services (EPCIS) standard defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. In addition, the EPCIS standard also incorporates data standards for how to populate EPCIS data elements.

The Core Business Vocabulary (CBV) provides data standards for populating EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies and element values (with definitions).

For downstream trading partners to make use of serial numbers applied at the unit level, manufacturers should expect to provide the parent-child hierarchy of each serialized shipping container to its serialized unit contents by means of an electronic message (EPCIS events or another method, depending on the capabilities of your customer) at the time of shipment. The data encoded in the bar code should exactly match the electronic data being passed between trading partners. For more information on how to use EPCIS for DSCSA, see the GS1 US DSCSA Implementation Suite.

LINEAR BAR CODES

As discussed for homogeneous cases, the product identifier may be in either a linear or a 2D Data Matrix bar code.[64] Additionally, FDA's bar code rule, 21 C.F.R. § 201.25,[65] has long required certain drug products to bear an encoded, standardized linear bar code containing the NDC number.[66] The bar code must contain, at minimum, the product's NDC in a format that meets GS1 or HIBCC standards, or such other standards that FDA might set.[67]

As explained in the section on "The Product Identifier," a GS1-compliant linear bar code is created by affixing the prefix "3," followed by the drug package's NDC, followed by a modulo-10 check digit, to create the complete GTIN-12 code. See GS1 General Specifications, for detailed dimensions associated with the formats shown below.

Figure 18

UPC prefix "3"	NDC	Check Digit
3 0001-4096-60 1	3 11111-569-73 8	3 22222-8395-5 9

Note: GS1 HRI rules would not allow use of "N". The second set of examples shown for the UPC barcode with "N", as some barcode software will automatically create it. *(See page 18.)*

64. The 2015 version of the FDA bar code rule is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.25 (retrieved May 3, 2017). In August 2016, FDA amended the bar code rule effective November 29, 2016 [81 Fed. Reg. 60169, 60177 (Aug. 31, 2016)]. The current version of the rule, as of May 2017, is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved May 3, 2017).

65. 21 C.F.R. § 610.67 applies the standards of 21 C.F.R. § 201.25 to biologics. A separate FDA rule mandating standardized data structures and bar codes on blood and blood products is beyond the scope of this document [see 21 C.F.R. § 606.121(b)(13)].

66. The older version of the rule had specified only GS1 or HIBCC standards. In its August 2016 amendment to the rule, FDA added that, effective November 29, 2016, the agency could, if it elected to do so, approve bar code standards and formats other the GS1 or HIBCC standard (81 Fed. Reg. at 60177). The revised bar code rule reflecting this amendment (21 C.F.R. § 201.25) is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved May 17, 2017).

67. § 582(a)(3)(A)(ii), § 21 U.S.C. § 360eee-1(a)(3)(A)(ii); though FDA is required to issue guidance, as of May 2017 the agency has not weighed in on how to seek exceptions from DSCSA requirements due to package sizes being too small.

BAR CODES ON VERY SMALL PACKAGING CONFIGURATIONS

Products Intended for Individual Resale

The DSCSA requires that by November 27, 2017, homogeneous cases and all products down to the individual saleable unit must bear a product identifier unless a manufacturer or repackager obtains an exception from the FDA for packages that are too small to accommodate the required information.[68] If not exempt, even very small packages must have the product identifier in a 2D Data Matrix bar code if intended for resale. Additionally, under the bar code rule, 21 C.F.R. § 201.25, all labelers must apply a linear bar code to the prescription drugs they commercially distribute.

Linear Bar Codes for Products Not Intended for Individual Resale

If the unit is not for individual resale, such as one vial in a box of 20 where the individual unit is not offered by the manufacturer or repackager for sale, it would not need to be individually labeled with a human and machine-readable product identifier in a 2D Data Matrix as required under the DSCSA.[69]

However, the FDA's linear bar code rule, 21 C.F.R. § 201.25 may still apply. Under the linear bar code rule, labelers (including manufacturers, repackagers, etc.) must apply a linear bar code to their prescription drugs, including unit-dose, unit-of-use and other very small packages, that they commercially distribute and regardless of whether the individual unit is offered for sale.

Additionally, each registrant must list and obtain a unique NDC number for each drug that it manufactures, repacks, relabels or salvages for commercial distribution.[70]

The linear bar code must include at least the drug's unique NDC. In addition, there are several healthcare organizations urging pharmaceutical manufacturers to offer all products in unit-of-use and/or unit-dose packaging configurations, and to provide a standardized bar code at these packaging levels. According to these organizations, a standardized bar code should appear on the labels of drug products at all levels of use, from the largest bulk to the smallest single-unit containers.

For packaging below the level of the individual saleable unit, such as unit-dose and unit-of-use packaging, these guidelines recommend that manufacturers and repackagers assign GTINs for each distinct packaging level (by assigning a different non-zero indicator digit) and configuration based upon the NDC number listed for the product with the FDA.[71] Package size segment of the NDC would reflect the small configuration and it would be encoded, as discussed above in "Configuring the NDC in Bar Codes," in the GTIN-12 data structure, where the NDC is preceded by the GS1 US prefix "3" and followed by the modulo-10 check digit.

If the package size supports the relatively larger UPC symbol, then UPC-A is the preferred data carrier because almost every bar code scanner can read it. Methods of representing a linear bar code on very small packages are discussed in the next section.

68. Under the DSCSA, a "package" means 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. An "individual saleable unit" is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser; see § 581(11), 21 U.S.C. § 360eee(11).

69. 21 C.F.R. § 207.41; the NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017).

70. GS1, Healthcare GTIN Allocation Rules (December 2015). Retrieved from http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf.

71. The NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 and the bar code rule is available at https://www.law.cornell.edu/cfr/text/21/201.25 (retrieved on May 3, 2017).

Alternate Linear Bar Code Symbology for Very Small Packages

These guidelines previously recommended GS1 DataBar (GS1 DataBar Limited and GS1 DataBar Stacked) as alternative data carriers. However, there has been some negative feedback regarding the ability of some older scanning systems to read these bar codes particularly in the retail pharmacy setting but generally not in the institutional/hospital setting. This limitation at retail can usually be overcome through reconfiguration of the scanning device; however, the use of either truncated or reduced UPC-A may improve scanning capability without reconfiguration, and is currently widely used in the supply chain. Truncated UPC-A data carriers are altered from the standard GS1 specifications by changing the height of the bar code. Reduction of UPC-A data carriers are altered from the standard GS1 specifications through percent reduction in overall size. A reduced U.P.C-A generally tends to be more easily read than a truncated UPC-A. Reducing UPC-A below 80 percent should only be considered if space restrictions will not accommodate a larger data carrier, and should never be used in a retail environment. Truncation and reduction can be combined as necessary to achieve the desired sizing.

Figure 19

Note: GS1 HRI rules would not allow use of "N". The second set of examples shown for the U.P.C barcode with "N", as some barcode software will automatically create it.

It should be noted that the 10-digit HIBCC Small Package Symbol — as defined in ANSI/HIBC 2.3-2009, The Health Industry Bar Code (HIBC) Supplier Labeling Standard — also is slightly smaller than a UPC symbol of the same X-dimension and would be compliant with the FDA bar code rule, 21 C.F.R. § 201.25, but not with GS1 Standards.[72]

72. § 582(a)(9)(A), 21 U.S.C. § 360eee-1(a)(9)(A).

BAR CODING ON PACKAGING CONFIGURATIONS LARGER THAN INDIVIDUAL SALEABLE UNITS

Inner Packs (Bundles)

The DSCSA requires product identifiers in a 2D Data Matrix bar code on individual saleable units and a 2D Data Matrix or linear bar code on homogeneous cases. It does not require the product identifier to be encoded onto inner packs (unless the pack is an individual saleable unit), though a trading partner could opt to do so if it desired.

If inner packs (also known as bundles, sleeves, trays, etc.) are labeled, these guidelines recommend including, at minimum, a 2D GS1 DataMatrix and a corresponding human-readable format The GS1 DataMatrix should encode the HRI listed: AI(01) GTIN + AI(21) Serial Number + AI(17) Expiration Date + AI(10) Lot Number. See the following example, noting that the layout below is only one potential variation.

A unique GTIN — distinct from the GTIN assigned to the unit of sale and distinct from the GTIN of the homogeneous case pack — would be necessary for the inner pack. These guidelines recommend adding a bundle label where the product is shrink wrapped. Some systems or cameras will have difficulty reading through shrink wrap unless the bundle is secured in a good position or a stretch bundle is used. Additionally, making the 2D bar code visible from the top in shrink wrap is recommended as a best practice.

Figure 20

Note: The example here does not encode the quantity and only represents one potential variation of an inner-pack label.

Homogeneous Cases

DSCSA Product Identifier

The DSCSA requires that the product identifier appear in either a linear or a 2D Data Matrix bar code and be affixed to, or imprinted upon, a homogeneous case.[73]

For bar code marking on cases, the industry traditionally has followed the guidelines set forth by GS1 specifying the GTIN in 14-digit format carried by Interleaved 2 of 5 or GS1-128 symbologies. However, the Interleaved 2 of 5 (or ITF-14) symbology is limited to carrying the GTIN in 14-digit format exclusively and cannot accommodate either a unique case serial number or any secondary information (such as the DSCSA-required expiration date and lot number in the product identifier, or quantity). These guidelines, therefore, no longer recommend the use of ITF-14. Instead, a combination of both GS1-128 and GS1 DataMatrix (with AIs as discussed above) should be the symbologies used at the homogeneous shipping case levels.

GUIDELINE RECOMMENDATION

These guidelines no longer call for the use of ITF-14. Instead, GS1-128 and GS1 DataMatrix should be the symbologies used at the shipping case level.

For a homogeneous case, these guidelines recommend a format that includes two distinct GS1-128 bar codes on the label (one placed directly above the other) and one GS1 DataMatrix bar code.

The GS1 DataMatrix on the homogeneous case should be the encoded product identifier (GTIN, unique serial number for the case, expiration date, lot number). Note that if the GS1 DataMatrix is affixed to a homogeneous case, the DSCSA's requirements for affixing a product identifier are satisfied. If the GS1 DataMatrix with encoded product identifier is not used, the DSCSA requires that a homogeneous case bear a linear bar code encoded with the same information.

- On a homogenous case label, the HRI should presented as:
  - GTIN
  - S/N
  - LOT
  - EXP
  - Other appropriate abbreviations are discussed in *pages 16–18*
- In the Product Identifier Final Guidance, it appears that FDA expects the NDC number in the human-readable portion of the product identifier and that the manufacturer or repackager may optionally include the GTIN.

73. Under these guidelines, a partially filled case containing the same product with same lot number and expiration date (each individually bearing an appropriate 2D Data Matrix bar code) is not a "homogeneous case" under the DSCSA, because the quantity of the partial case is variable. A case containing a varying and inconsistent number of individual saleable units could not be assigned a GTIN under GS1 standards and could not have a product identifier under the DSCSA. For these reasons, the guidelines recommend including a GS1-compliant SSCC for partial cases containing the same product, with the same expiration date and lot number.

GUIDELINE RECOMMENDATION

The HDA Bar Code Task Force does not recommend omitting the GTIN with the NDC embedded within it from the HRI. Though the Product Identifier Final Guidance would seem to permit the NDC alone in the human readable portion of the product identifier, these guidelines do not recommend presentation of the NDC alone.

- Per the Product Identifier Final Guidance, some companies may elect to include both the NDC and the GTIN in the HRI. If companies choose to include both the NDC and the GTIN in the HRI, the recommended order for printing the human readable is NDC, GTIN, Serial Number, Lot, Expiry. If a company elects to not include the NDC in the human-readable portion of the product identifier, the NDC, in its three-segment format, should appear elsewhere on the case label.

- The primary homogeneous case GS1-128 bar code (bottom bar code) encodes the GTIN and the case serial number. These guidelines suggest that the encoded data in the case primary GS1-128 linear bar code should appear as: <FNC1> + AI(01) + GTIN + AI(21) + Serial Number.

- The secondary case bar code (top bar code) encodes the expiration date, lot number and quantity (optional). These guidelines suggest that encoded data in the case secondary GS1-128 linear bar code should appear as: <FNC1> + AI(17) + Expiration Date + AI(10) + Lot Number + <FNC1> + AI(30) +Case Quantity.

  - It is recognized that AIs (10) and (17) must be processed together with the GTIN of the trade item to which they relate; this implies that these element strings must be encoded in the same data carrier as the GTIN. However, with insufficient space on a case label for a single bar code containing all elements (GTIN, SN, LOT, EXP) this guideline recommends breaking these elements into two separate bar codes.

  - Note that if the manufacturer or repackager elects not to affix the product identifier to a homogeneous case using a 2D Data Matrix (these guidelines recommend the GS1 DataMatrix), the labeler must use a linear bar code. During a transition period where the historical GS1-128 primary and secondary linear bar code symbols are still in use, case quantity using AI(30) in the secondary symbol may continue to be used. However, inclusion in the GS1 DataMatrix symbol of the explicit case quantity represented by AI(30) is not in accordance with GS1 General Specifications and is no longer permitted.

Homogeneous Case: Product Identification Label

Homogeneous cases should unambiguously identify the product and the (optional) quantity contained in the case. Homogeneous cases should be labeled in this way for many reasons. Among those:

- Handling, storing and picking require workers and automatic identification systems to be able to determine case contents quickly and accurately;

- Readability inside a truck trailer and warehouse environment is crucial for efficiency and error prevention; and,

- Drug Enforcement Administration (DEA) regulations must be followed when labeling scheduled drugs.

These guidelines recommend marking the following information on a product identification label, located on each trade-item case (a Standard Product Grouping in GS1 terminology):

1. Trade name of the product (if applicable) printed 0.5 inch in height or larger if possible. Controlled substances may or may not be identified for security reasons in accordance with the labeler's policy and/or DEA regulations;
2. Product strength (augmentation with large print can be helpful);
3. NDC number in human-readable form;
4. Storage requirements, such as minimum and maximum temperature range;
5. Manufacturer and/or distributor name;
6. Expiration date, lot number and quantity in GS1-128 bar code with appropriate HRI per GS1 specifications;
7. NDC number embedded in a GTIN which is encoded in a 14-digit format plus concatenated case serial number in GS1-128 bar code with appropriate HRI per GS1 specifications; and,
8. NDC number, case serial number, expiration date and lot number in GS1 DataMatrix bar code. No HRI is required provided the proper HRI accompanies the two GS1-128 bar codes. However, where the case is the lowest saleable unit, it may be helpful to include HRI for consistency.

Note, if your company chooses to add an internal use bar code, it is a best practice to:

- Specifically label it "for internal use" or bracket it so that it is not confused with other identifying bar codes;
- Space it from other bar codes so that it is clearly separate and distinguishable;
- Use a carrier other than a GS1 bar code so that they can be excluded from scanning logic; and,
- Place it on the bottom of a bottle or at least an opposite face so that they are not read.

Homogeneous Case Label: Product Identification Label Placement and Corner Wrap Examples

GUIDELINE RECOMMENDATION

Product identification labels are recommended on two adjacent sides of the case. **This can be achieved by using a wrap-around label or using two separate but identical labels on adjacent sides**. A 4-by-10-inch corner wrap label is the industry standard for a standard case size. Smaller size corner wrap labels can be used if necessary to accommodate for smaller case sizes. (See following case label samples.)

These guidelines recommend corner wrap labels for DSCSA serialization-compliant labeling. This reduces the likelihood that two different serial numbers could be present on the same package (eliminating the possibility that two labels, with differing serial numbers, could be applied to the same case). When using wrap-around labels, care must be taken to ensure that label placement is accurate and that no bar code or its minimum required quiet zone is positioned bent around the corner of the case. The bar codes and their associated quiet zones must not be obscured and must be readily scannable on each side of the shipping case.

Note that a single product identification label on one side of a shipping case is not acceptable. Product identification labels are recommended on two adjacent sides. Care should be taken when packing cases on a pallet to ensure that at least one product identification label is visible on any case with a side facing the exterior of the pallet load.

As depicted in Figure 21, product identification labels should be placed with the bar codes oriented in the "picket fence" orientation relating to the bottom of the case. That is, the bars should be perpendicular to the bottom edge of the case. The bottom edge of the label should be no closer than 1.25 inches from the bottom of the case. The corner wrap label should be placed on a corner of the case 1.25 inches from the bottom of the case. The center of the corner wrap label should be placed on the corner of the case. As previously noted, care must be taken to ensure that there is a sufficient bar code quiet zone in the center of the label and that the bar codes on both halves of the label are readily scannable once the label is affixed to the case. If the labeler uses two separate product identification labels, they should be affixed to the carton so that they mimic a wrap-around label. When using a non-corner wrap case label, the labels should be placed 0.75 inches from the shared corner and 1.25 inches from the bottom of the case.

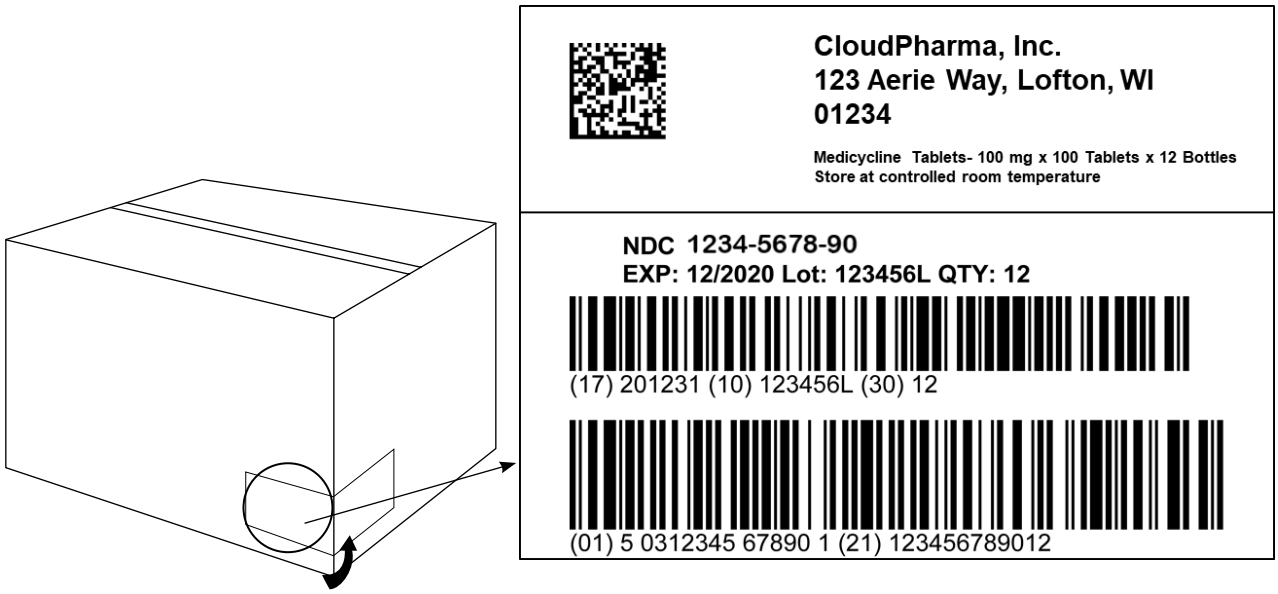


Figure 21

Pharmaceutical distributors receive inquires regularly from their customers asking which company was the labeler of a particular product. To ensure accurate and efficient disclosure, this information should be included on the case label as "Produced by" or "Distributed by" names.

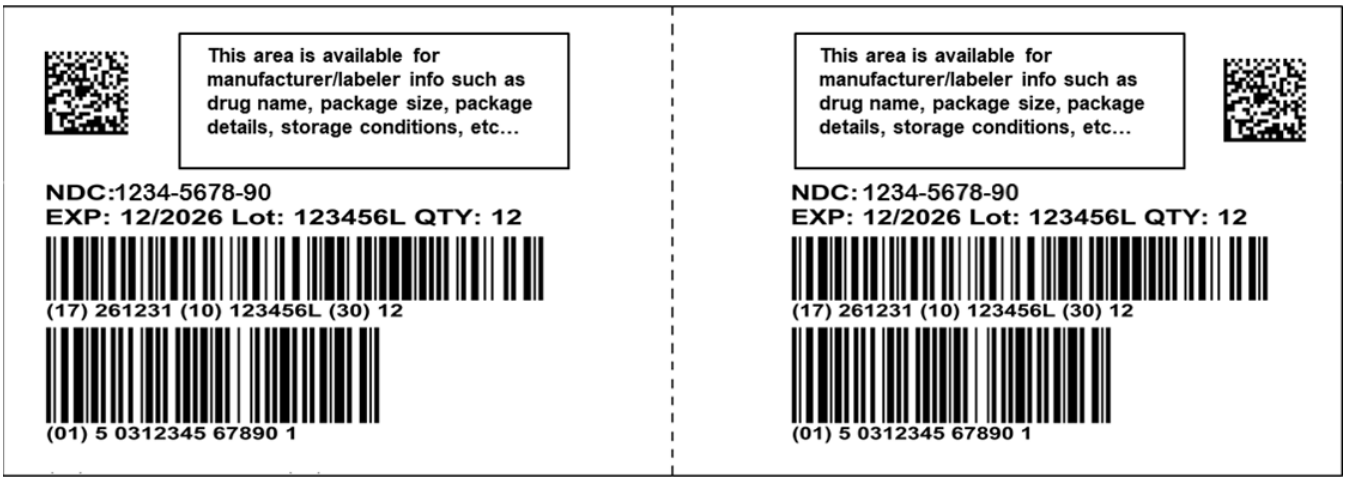


Figure 22

Option 1: Above is the HDA-recommended, 4-by-10-inch corner wrap case label. Note that some companies may print the NDC on package labels, either because they have an NDC number for the case or pallet or for commercial purposes.

Figure 23

Option 2: Above is the HDA-recommended 4-by-10-inch corner wrap case label with no product description to be used with DEA controlled substances

WRAP-AROUND PRODUCT IDENTIFICATION LABEL – HOMOGENEOUS CASE, SERIALIZED Label Size is 4.00 by 10.00 inches. The X-dimension of the GS1-128 symbols is 20.0 mils. GS1 DataMatrix symbol X-dimension is 30.0 mils. Primary GTIN + Serial Number is 0.75" tall; secondary EXP + LOT + QTY is 0.50" tall. Bar code HRI below the GS1-128 symbols is 12 point. EXP/LOT/QTY text above top secondary data symbol also is 12 point In the example shown above, the data used results in a 22x22 GS1 DataMatrix, therefore 0.66"x0.66", plus a mandatory quiet zone. All symbols encode FNC1 in the first position and FNC1 as the mandatory field delimiter where required.

The wrap-around label shown above is reproduced below in actual size. Below is one half of the wrap-around label depicted above but reproduced at 100 percent size. The right half is identical to the left. Actual size is 4 by 5 inches on each side or 4 by 10 inches overall.

Figure 24

In some instances, companies also may choose to use a Segmented GS1 DataMatrix on a homogenous case. To understand how to use these bar codes, see the GS1 General Specification for additional details.

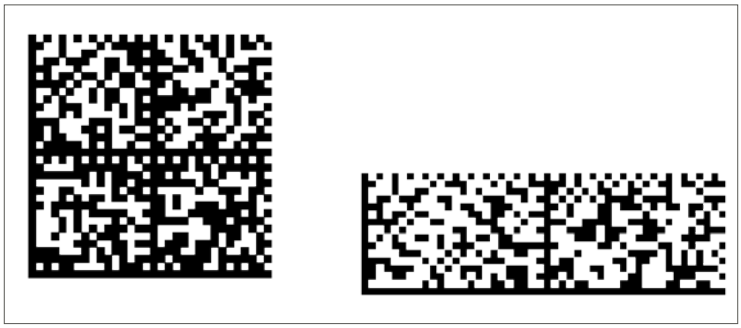


Figure 25

HDA Shipping Case Product Identification Label: Summary Specifications

In Figure 26, which follows, the essential characteristics of these guidelines recommended shipping case product identification label requirements for Format 1 (Serialized Product); and Format 2 (Non-Serialized Product). It is imperative to maintain at least the minimum X-dimension and symbol height specified in the table. In general, the largest possible X-dimension that will fit in the space available should be used. The use of bar code symbols with an X-dimension below the specified minimum may result in substantially reduced "scannability" and disruption to the supply chain.

Adherence to all the technical requirements is essential. Often overlooked is the necessity of at least the minimum clear area or "quiet zone" to the left and right of the GS1-128 symbols (and on all four sides of the GS1 DataMatrix symbol). A "perfectly printed" symbol without the necessary minimum "quiet zones" can be just as unscannable as a symbol printed partially off the label.

2022 HDA Shipping Case Product Identification Label – Summary Specifications Bar Code Symbologies, Encoded Data Elements, Human-Readable Interpretation (HRI) & Print Quality

Important Parameters		Format #1 SERIALIZED PRODUCT	Format #2 NON-SERIALIZED PRODUCT
Symbology (see Note 1)	Primary:	GS1-128 (incl. FNC1 where req'd)	Same as serialized product
	Secondary:	GS1-128 (incl. FNC1 where req'd)	
	(2D) Prim + Exp & Lot:	GS1 DataMatrix (incl. FNC1 where req'd)	
Encoded Data Elements (see Note 2 and Note 3)	Primary:	GTIN-14 + SN (aka sGTIN): AI(01)+AI(21)	GTIN-14: AI(01)
	Secondary:	EXP + LOT + QTY: AI(17)+AI(10)+AI(30)	EXP + LOT + QTY: AI(17)+AI(10)+AI(30)
	(2D) Prim + Exp & Lot:	GTIN-14 + SN + EXP + LOT AI(01)+AI(21)+AI(17)+AI(10)	GTIN-14 + EXP + LOT AI(01)+AI(17)+AI(10)
GS1-128 Bar Code Symbol X-dimension Primary & Secondary	Preferred:	16.7-30.0 mils (0.0167-0.0300 in.)*	Same as serialized product
	Minimum:	13.3 mils (0.0133 in.)*	
		*Use largest X-dim that will fit on the label, but no smaller than the minimum X-dimension.	
GS1-128 Bar Code Symbol Height Primary & Secondary (Increased height can improve scannability)	PRIMARY	GTIN-14 + SN (aka sGTIN): AI(01)+AI(21)	GTIN-14: AI(01)
	Preferred:	0.75 inches	0.75 inches
	Minimum:	0.5 inches	0.5 inches
	SECONDARY	EXP + LOT + QTY: AI(17)+AI(10)+AI(30)	EXP + LOT + QTY: AI(17)+AI(10)+AI(30)
	Preferred:	0.5 inches	0.5 inches
	Minimum:	0.4 inches	0.4 inches
GS1 DataMatrix (2D) Bar Code X-dimension	Preferred:	30.0 mils (0.0300 in.)	Same as serialized product
	Minimum:	30.0 mils (0.0300 in.)	
Bar Code Quiet Zones - MINIMUM Width	GS1-128	10X (10 times X-dim; 0.20" min. recommended)	Same as serialized product
	GS1 DataMatrix	3X (3 times X-dim; 0.10" min. recommended)	
Bar Code Quality - MINIMUM Grade	GS1-128	1.5/10/660 (per GS1 & ISO/IEC 15416)	Same as serialized product
	GS1 DataMatrix	1.5/20/660 (per GS1 & ISO/IEC 15415)	Same as serialized product
Position of Bar Code Symbols on Label	(2D) Prim + Exp & Lot:	GS1 DataMatrix, the Upper Label Corner Farthest from the Case Corner Edge	Same as serialized product
	Secondary:	GS1-128, Directly Above Primary Symbol	
	Primary:	GS1-128, Bottom of Label	
Bar Code Human-Readable Interpretation (HRI) Position & Size	(2D) Prim + Exp & Lot:	None (though data is NOT IDENTICAL to Prim. & Sec.)	Same as serialized product
	Secondary:	Below GS1-128, 10 point (8 point min.)	
	Primary:	Below GS1-128, 10 point (8 point min.)	
Secondary Data DESC.	Secondary:	Above GS1-128, 12 point (10 point min.)	Same as serialized product
Printing Process and Substrate	All Labels	Thermal Transfer Pressure-sensitive Label	Same as serialized product
Label Skew	All Labels	+/- 2 Degrees from Horizontal** **Approx. 0.15 inch Across a 4" Wide Label	Same as serialized product

Note 1: Primary (sGTIN) and full secondary (EXP+LOT+QTY) data in separate GS1-128 symbols are required. In addition, primary (sGTIN) and some secondary (LOT & EXP only) data are combined and encoded in a required 2D GS1 DataMatrix symbol.

Note 2: GS1-128 & GS1 DataMatrix symbols encode FNC1 at the beginning of the symbol; and as a variable-length field delimiter, as required.

GTIN+SN: FNC1+AI(01)+GTIN+AI(21)+SN
EXP+LOT+QTY: FNC1+AI(17)+EXP+AI(10)+LOT+FNC1+AI(30)+QTY
GTIN+SN+EXP+LOT: FNC1+AI(01)+GTIN+AI(21)+SN+FNC1+AI(17)+EXP+AI(10)+LOT

Note 3: The GS1 DataMatrix symbol does NOT include AI(30)+QTY as an encoded data element. Inclusion in the GS1 DataMatrix symbol of the explicit case quantity represented by AI(30) is NOT in accordance with GS1 General Specifications. AI(30)+QTY should NOT be encoded in the GS1 DataMatrix symbol. However, during a transition period where the historical GS1-128 primary and secondary linear bar code symbols are still in use, the case quantity represented by AI(30) should continue to be encoded in the GS1-128 symbol carrying secondary data.

Updated 22 January 2022

Figure 26

Production Identification Label Formats

LABEL FORMAT 1: SERIALIZED PRODUCT

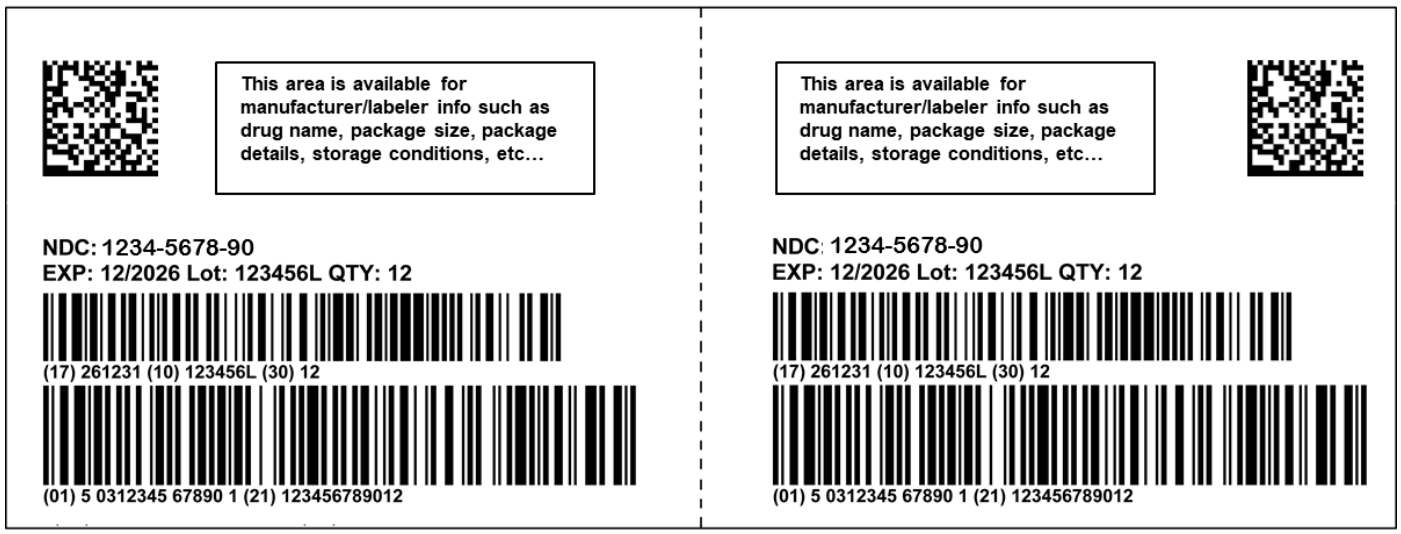
This guideline specifies two distinct GS1-128 symbols, which are both mandatory. One symbol is placed directly above the other, as has been the custom practice since 2005. The bottom symbol contains the item identification (primary) data and encodes the GTIN using AI(01), plus the unique case pack or shipping container serial number (SN) using AI(21). The top symbol contains item attribute (secondary) data and encodes expiration date using AI(17), lot number using AI(10) and the optional quantity using AI(30).

Note that during a transition period, when the historical GS1-128 primary and secondary linear bar code symbols are still in use, case quantity using AI(30) in the secondary symbol will continue to be the recommended practice. However, inclusion in the GS1 DataMatrix symbol of the explicit case quantity represented by AI(30) is not in accordance with GS1 General Specifications and GS1 standards no longer permit it. When other AIs are encoded in addition to the four DSCSA required data fields [(01) + (21) +(17) + (10)], the HDA Bar Code Task Force recommends that the DSCSA required fields be first in the order, only then followed by the optional field(s). In the case of AI 7004 and other AIs, the order of encoding this data should be after 4 PI elements. The GS1 DataMatrix symbol does not replace the two linear bar codes. These same format options apply to Format 2 (Non-Serialized Product).

GUIDELINE RECOMMENDATION

As companies begin to serialize product, the guidelines recommend product identification labels follow Format 1 — GTIN, serial number, expiration, lot number and, if necessary, quantity — as described in this section. Inclusion in the GS1 DataMatrix symbol of the explicit case quantity represented by AI(30) is not in accordance with GS1 General Specifications and GS1 standards no longer permit it. However, during a transition period where the historical GS1-128 primary and secondary linear bar code symbols are still in use, case quantity using AI(30) in the secondary symbol will continue to be used.

Figure 27



Note that in addition to the FNC1 character required to be encoded in the first position of any GS1-128 symbol, an FNC1 character must be encoded as a separator character to delineate the end of the AI(10)

data field from the subsequent AI(30) in the secondary bar code [or to delineate the end of the AI(30) data field from the subsequent AI(10) if AI(30) comes before AI(10)]. The FNC1 separator character will be automatically decoded, translated and transmitted by a scanner as <GS> or Group Separator (ASCII 29), as indicated by the GS1-128 symbology specification. The FNC1 character at the beginning of the symbol has another purpose and is never transmitted.

The GS1 DataMatrix symbol can be scanned by trading partners equipped with appropriate camera-based imagers (scanners) throughout the supply chain — from manufacturer, to distributor to the hospital receiving dock. It enables those who choose to scan it to capture all the data elements in a single scan. Note that a FNC1 symbol character must be encoded to delineate the AI(21) data field from AI(17) as noted above. The FNC1 separator characters should be automatically decoded, translated and transmitted by a scanner as <GS> or Group Separator (ASCII 29), as per the GS1 DataMatrix symbology specification.

GUIDELINE RECOMMENDATION

The GS1-128 and GS1 DataMatrix symbols should be printed as black bars on a white pressure-sensitive label using the thermal-transfer printing process or a similar method. Thermal transfer printing generally provides the best contrast and overall bar code print quality. While GS1 standards have indicated black on white printing as a possible source of lower grading with older printing technology, it is important to note that newer technology has emerged that produces white on black labels with improved precision durability. Trading partners should work together to ensure appropriate grading checks and results are used to avoid and identify potential sources of scanning issues. Care always must be taken to ensure that print speed and head temperature are correctly set and that the thermal printhead is clean and free of "dead dots," that is, thermal printhead elements that do not work and cause blank streaks or voids along the length of the printed label, which can cause symbols to be unreadable.

The nominal GS1-128 symbol X-dimension in this application is 15–20 mils. The lower GTIN symbol is printed taller than the upper symbol to denote its primacy. The nominal height of the lower symbol is 0.75 inches while the nominal height of the secondary bar code is 0.5 inches. The nominal (and minimum) GS1 DataMatrix symbol X-dimension in this application is 30 mils (see Figure 26).[74]

The HRI of the primary GTIN + Serial Number bar code should be printed directly beneath the bar code.

Figure 28

Elements of these include (in this order):

- The GTIN Application Identifier in parenthesis "(01)";
    - The indicator digit ("5" in the examples herein);
    - The two-digit "03" GS1 prefix for an NDC embedded within a GTIN;
    - The NDC itself;

74. Some scanners may require additional configuration or programming to accurately capture the Group Separator and allow the receiving system to accurately consume the data.

- The GTIN mod-10 check digitcalculated from the preceding 13 digits;
- The serial number application identifier in parenthesis "(21)"; and,
- The serial number data.

Each of these elements should be separated by a single space. The font size of this human-readable string is 10 points.

The HRI of the secondary bar code expiration date, lot number and quantity bar code shall be printed directly beneath the bar code. The preferred format of this data (in this following order) is:

- The expiration date AI in parentheses "(17)";
- The expiration date data;
- The lot number AI in parentheses "(10)"; followed by
- The lot-number data; and,
- The quantity AI in parentheses "(30)," followed by the quantity data.

Each of these distinct elements should be printed with proper encoding so that they can be parsed correctly in any order and separated by a single space. The nominal font size of this human-readable string is 10 points. However, if GS1-128 secondary/item attribute data elements are encoded as AI(17) + AI(30) + AI(10) then the order of these human-readable data elements should be the same — that is, expiration date AI in parentheses "(17)" followed by the expiration date data; the quantity AI in parentheses "(30)" followed by the quantity data; and the lot number AI in parentheses "(10)" followed by the lot number data.

A more explicit representation of the data encoded in the secondary bar code is generally printed (in non- HRI text) directly above the bar code. This string typically begins with the field label "EXP:" followed by a space and the expiration date with the year displayed as "CCYY" and the month and day, as appropriate; then three spaces and the field label "LOT" followed by a space and the lot number; then the field label "QTY:" followed by a space and the quantity data as encoded in the bar code, including any leading zeros. The accepted nominal font size for this human-readable string is 12 points.

An HRI of the GS1 DataMatrix symbol is not required since this text is available elsewhere on the label.

Recognizing that there is a wide variety of shipping case sizes, these guidelines depict three product identification label templates or sizes that represent the optimal arrangement of the various data elements and maximization of bar code X-dimension, height and HRI. In every case, the preferred embodiment is the largest of these three label templates, which is compatible with the shipping case. Labelers are urged to review their shipping case labeling capabilities and to adhere to this recommendation as closely as possible.

FORMAT 1 BAR CODE LABEL EXAMPLES

Primary Data GS1-128 Symbol:
Global Trade Item Number (GTIN): 50312345678901
NDC Embedded within GTIN: 1234-5678-90
Serial Number: 123456789012

Note: This is a representative 12-digit, all-numeric serial number that is compatible with GS1 serialized GTIN radio frequency identification (RFID) applications. Longer serial numbers or those with alpha characters will produce a longer length GS1-128 symbol than the above example. This may result in the necessity to use a wider label or a smaller X-dimension. Before using a smaller X-dimension, ensure that your GS1-128 symbol is optimized to produce the shortest possible symbol as described in the Code 128 symbology specification.

Secondary Data GS1-128 Symbol:
Expiration Date: December 2020
Lot Number: 123456L

Note: This is a representative lot number/code. Longer lot codes or those with more alpha characters will produce a longer length GS1-128 symbol than the above example. This may result in the need to use a wider label or smaller X-dimension. Before using a smaller X-dimension, ensure that your GS1-128 symbol is optimized to produce the shortest possible symbol as described in the Code 128 symbology specification.

Quantity: 144

Note: Quantity is often encoded with a single leading zero to create an even number of digits in the bar code data (e.g., "144" becomes "0144"). This technique can produce a shorter length GS1-128 symbol than encoding an odd-number quantity value directly.

Combined Primary and Secondary Data GS1 DataMatrix Symbol:

Note: The combined primary and secondary data string encoded in the 2D GS1 DataMatrix symbol must be the same AIs/data elements except for quantity and FNC1 separator characters that are encoded in the individual primary and secondary data GS1-128 symbols. See Note 2 in Figure 26 for the precise encoding model.

GTIN with Embedded NDC: 50312345678901
Serial Number: 123456789012
Expiration Date: December 2020
Lot Number: 123456L

FORMAT 1, EXAMPLE 1: PREFERRED MINIMUM LABEL SIZE

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, SERIALIZED CORNER WRAP

Label size is 4.00”x10.00”; GS1-128 X-dimension is 19.1 mils; GS1 DataMatrix X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.75” tall; secondary EXP + LOT + QTY is 0.50” tall. GS1 DataMatrix is a 22x22 matrix, therefore 0.66”x0.66”. HRI is 10-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY text is 12 point.

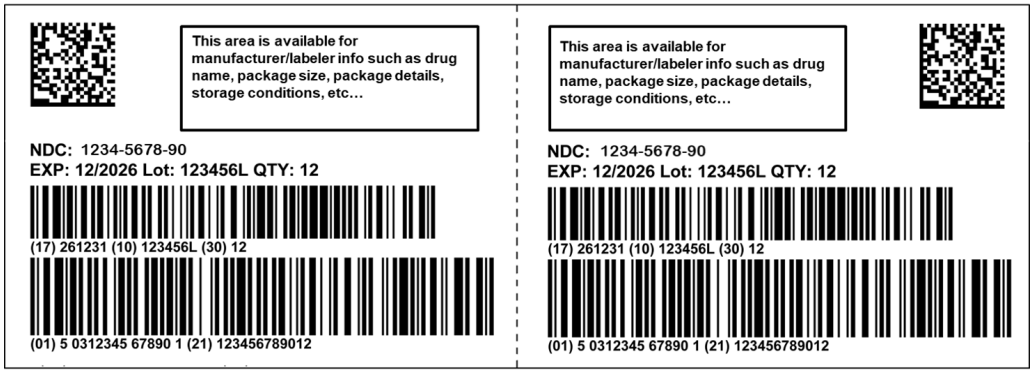


Figure 29

FORMAT 1, EXAMPLE 2: SMALLEST HEIGHT LABEL

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, SERIALIZED CORNER WRAP

Label size is 2.00”x10.00”; GS1-128 X-dimension is 15.8 mils; GS1 DataMatrix X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.50” tall; secondary EXP + LOT + QTY is 0.40” tall. GS1 DataMatrix is a 22x22 matrix, therefore 0.66”x 0.66”. HRI is 8-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY text is 10 point.

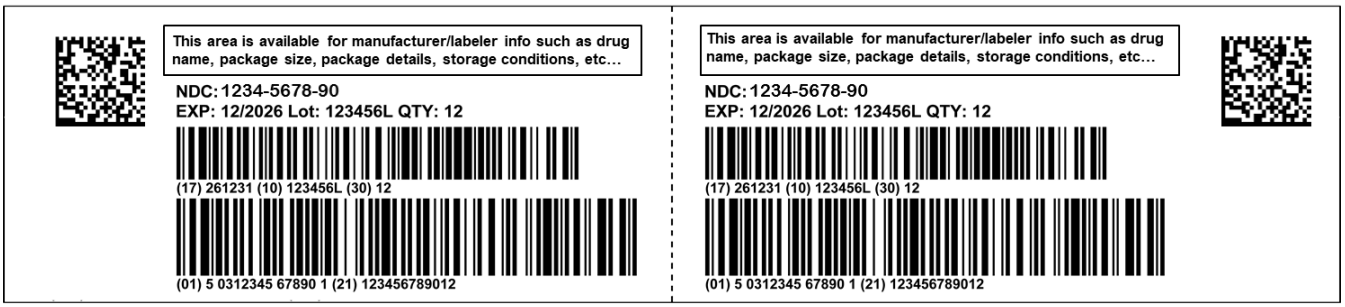


Figure 30

FORMAT 1, EXAMPLE 3: SMALLEST WIDTH LABEL

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, SERIALIZED CORNER WRAP

Label Size is 3.00” x8.00”; GS1-128 X-dimension is 14.1 mils; GS1 DataMatrix X-dimension is 30.8 mils. Primary GTIN + SN is 0.75” tall; secondary EXP + LOT + QTY is 0.50” tall. GS1 DataMatrix is a 22x22 matrix, therefore 0.66”x0.66”. HRI is 10-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY text is 12 point. *Note: Depending on the length of the serial number, and the possible use of alpha characters in the serial number, a smaller X-dimension may be required to fit this smallest width label. It is recommended that manufacturers/packagers submit sample labeling to their downstream trading partners for readability in these circumstances.*

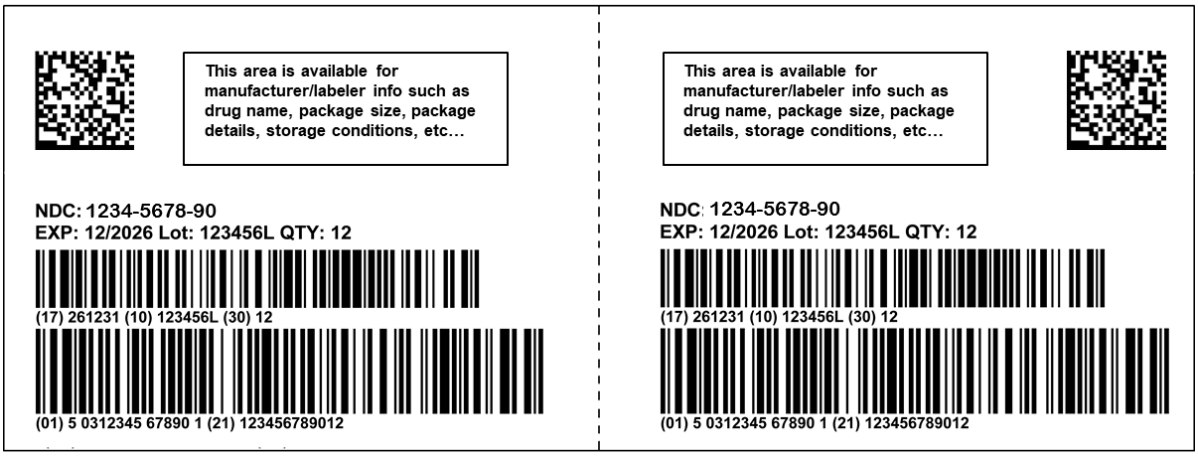


Figure 31

LABEL FORMAT 2: NON-SERIALIZED PRODUCT

Products that fall outside the scope of the DSCSA (such as OTC drugs) do not need to be serialized and are not required to bear a 2D Data Matrix bar code. However, manufacturers and labelers may want to affix GS1-compliant labels to the cases. GTIN specifies two distinct GS1-128 symbols, both of which are mandatory under GS1 standards. One symbol is placed directly above the other. The bottom symbol contains the item identification (primary) data and encodes the GTIN only using AI(01). Note that quantity using AI(30) is no longer encoded following the GTIN in the primary bar code. The top symbol contains item attribute (secondary) data and encodes expiration date using AI(17), lot number using AI(10) and quantity using AI(30) — or alternatively, AI(17) + AI(30) + AI(10). These same format options apply to Format 1 (GTIN + Serial Number). Examples are below.

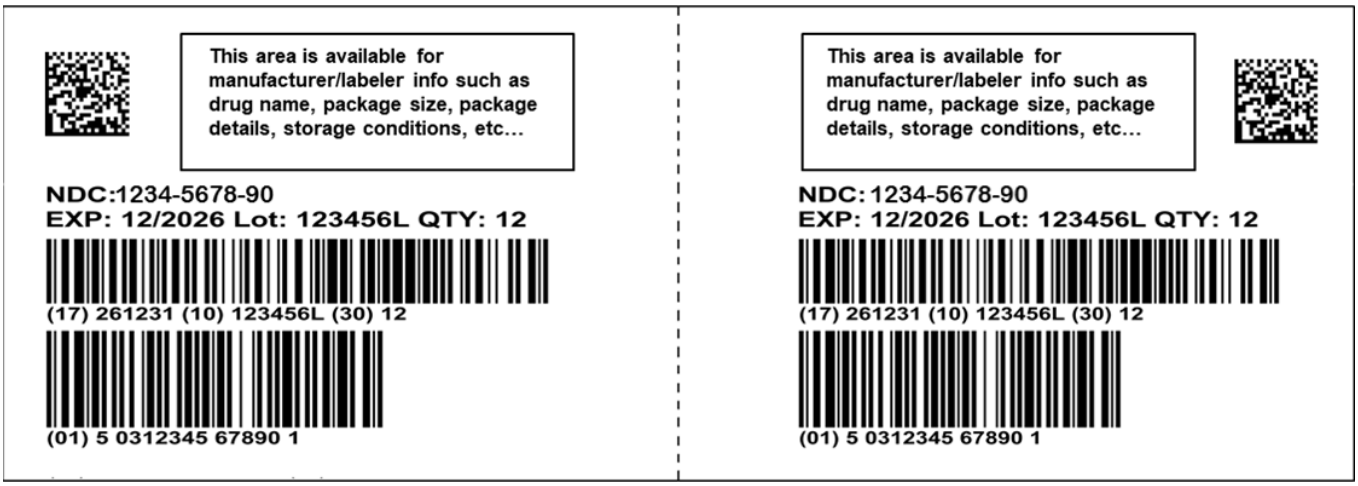


Figure 32

Note that in addition to the FNC1 character required to be encoded in the first position of any GS1-128 symbol, an FNC1 or ASCII (29) group separator character must be encoded to delineate the end of the AI(10) data field from the subsequent AI(30) in the secondary bar code. The FNC1 separator character will be automatically decoded, translated and transmitted by a scanner as <GS> or Group Separator (ASCII29), as per the GS1-128 symbology specification. The FNC1 character at the beginning of the symbol has another purpose and is never transmitted. This format also shows an optional but recommended GS1 DataMatrix symbol encoding the primary/item identification (GTIN), followed by secondary/item attribute data elements and their associated AIs.

FORMAT 2 BAR CODE LABEL EXAMPLES

Primary Data GS1-128 Symbol:
Global Trade Item Number (GTIN): 50312345678901
NDC Embedded within GTIN: 1234-5678-90

Secondary Data GS1-128 Symbol:
Expiration Date: December 2020
Lot Number: 123456L

Note: This is a representative lot number/code. Longer lot codes or those with more alpha characters will produce a longer length GS1-128 symbol than that shown. This may result in the need to use a wider label or smaller X-dimension. Before using a smaller X-dimension, ensure that your GS1-128 symbol is optimized to produce the shortest possible symbol as described in the Code 128 symbology specification

Quantity: 144

Note: Quantity often is encoded with a single leading zero to create an even number of digits in the bar code data (e.g., "144" becomes "0144"). This technique can produce a shorter length GS1-128 symbol than encoding an odd-number quantity value directly..

Combined Primary and Secondary Data GS1 DataMatrix Symbol:

Note: The combined primary and secondary data string encoded in the GS1 DataMatrix symbol should use the same AIs/data elements, except for quantity and FNC1 separator characters, as these are encoded in the individual primary and secondary data GS1-128 symbols. See Note 2 in Figure 26 for the precise encoding model.

GTIN with Embedded NDC: 50312345678901
Expiration Date: December 2020
Lot Number: 123456L

FORMAT 2, EXAMPLE 1: PREFERRED MINIMUM LABEL SIZE

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, NON-SERIALIZED CORNER WRAP

Label Size is 4.00"x10.00"; GS1-128 X-dimension is 19.1 mils; GS1 DataMatrix (GS1 DataMatrix is not required on Non-Serialized labels) X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.75" tall; Secondary EXP + LOT + QTY is 0.50" tall. GS1 DataMatrix is an 18x18 matrix, therefore 0.54"x0.54".HRI is 10-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY text is 12 point.

Figure 33A

Or:

Figure 33B

FORMAT 2, EXAMPLE 2: SMALLEST HEIGHT LABEL

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, NON-SERIALIZED CORNER WRAP

Label Size is 2.00"x10.00"; GS1-128 X-dimension is 15.8 mils; GS1 DataMatrix (GS1 DataMatrix is not required on non-serialized labels) X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.50" tall; secondary EXP + LOT + QTY is 0.40" tall. GS1 DataMatrix is a 18x18 matrix, therefore 0.54"x 0.54". HRI is 8-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY text is 10 point.

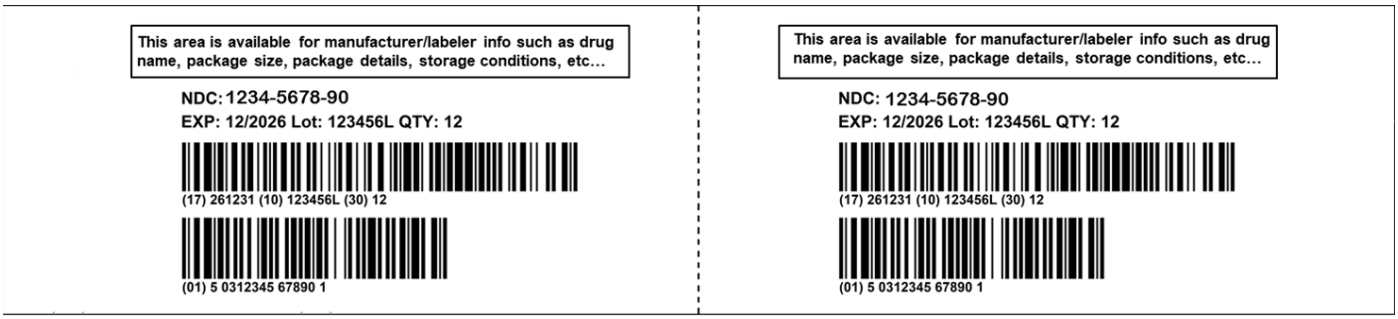


Figure 34A

Or:

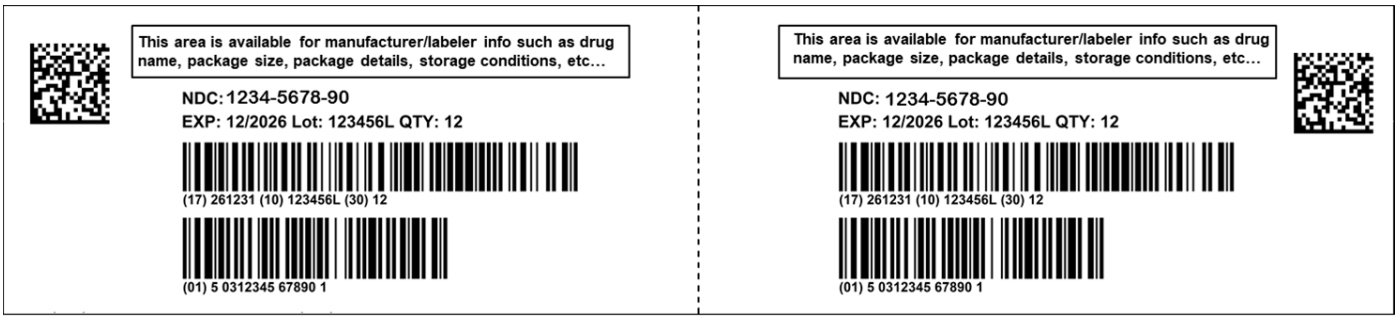


FIgure 34B

FORMAT 2, EXAMPLE 3: SMALLEST WIDTH LABEL

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, NON-SERIALIZED CORNER WRAP

Label Size is 3.00"x8.00"; GS1-128 X-dimension is 14.1 mils; GS1 DataMatrix (GS1 DataMatrix is not required on Non-Serialized labels) X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.75" tall; secondary EXP + LOT + QTY is 0.50" tall. GS1 DataMatrix is a 18x18 matrix, therefore 0.54"x 0.54". HRI is 10-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY text is 12 point.

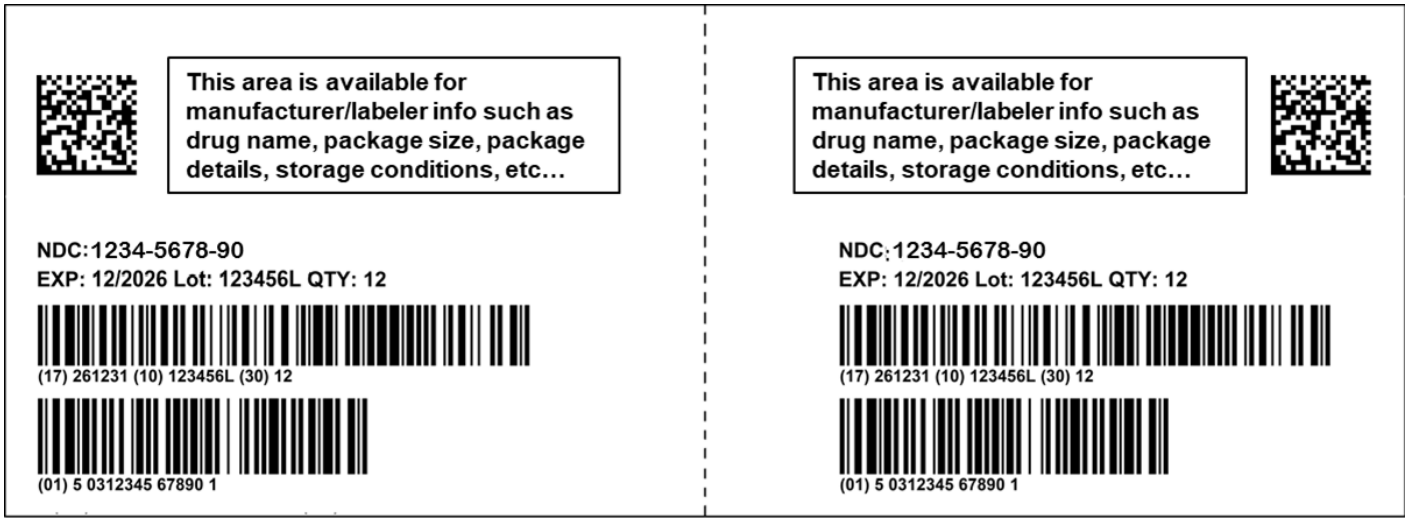


Figure 35A

Or:

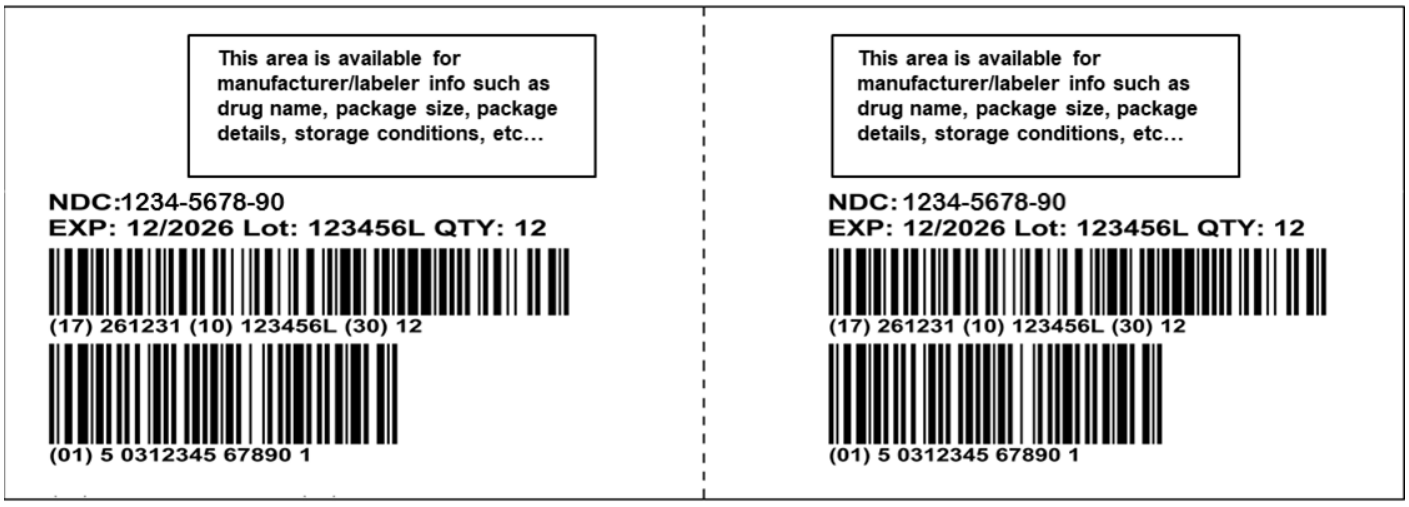


Figure 35B

Note: The sample symbols depicted in Format 1 GTIN + Serial Number and Format 2 GTIN encode valid data and are reproduced at 100 percent of actual size. The examples also conform to the recommended GS1-128 symbol minimum X-dimension for the available label width, GS1-128 symbol height for the available label height, GS1 DataMatrix minimum X-dimension (30 mils) and the position and arrangement of the HRI.

GUIDELINE RECOMMENDATION

Case Marking and Labeling

The preferred method of marking both product identification and transportation/logistics information is to print the requested information on a pressure-sensitive label. A pressure-sensitive label can be applied to any and all cases, thereby reducing the number of different cases a manufacturer must order and inventory. To maximize human and machine readability, the preferred color scheme is a white background with black printing. Colors are generally more difficult to for scanners to read. Other printing methods are acceptable, for example, laser ablation on a black code block presenting white image on a dark surface.

Exceptions are possible, such as augmented human-readable information, where a color other than black can be used to call attention to certain information that would improve handling efficiency and reduce errors. The label and printing should be water, smear and scuff resistant.

Partial Homogeneous Case and Non-Homogeneous Case

Partial Homogeneous Case, Internal Transfers

Manufacturers and repackagers may have internal business and inventory management reasons for wishing to affix a serialized label to homogeneous partial cases that are not changing ownership.

Homogeneous partial cases of products are not to be considered trade items when manufacturers and repackagers are transferring these less-than-full cases internally, such as from their packaging lines to their own warehouse/distribution center. Serialized labeling of partial cases can be a valuable means for aggregating serialized unit packages when performing this inventory movement. A manufacturer or repackager should decide internally on the utility and design of labels for partial cases. With no change of ownership, the products are not yet covered by the DSCSA. Manufacturers and repackagers may wish to affix serialized labels to the homogeneous partial cases to aid in inventory control and management. Note that the following example is only one possible configuration and any labeling of units for internal transfer is an individual business decision.

The following example includes a GS1 Serial Shipping Container Code (SSCC) and the word "partial." It is recommended that partial case labels not include a secondary linear bar code, so the design looks distinct from that of a full homogeneous case. Some manufacturers prefer to include a data carrier that provides information about the content of partial cases. In this instance, the linear bar code containing the SSCC-18 does not match the data encoded in the 2D Data Matrix. The following is an example of one means of providing such a data carrier. The 2D Data Matrix is encoded with AI(02), the GTIN of the contained items, AI (17), the expiration date, AI(10), the batch or lot number, and AI(37) the count of trade items. Note that this application of AI(02) and AI(37) is not recommended by GS1 US and is not intended for labeling of trade items. Although not pictured in the following label, some companies may print the NDC on package labels, either because they have an NDC number for the case or pallet or for commercial purposes. These guidelines recommend including the NDC in the "free-form" area.

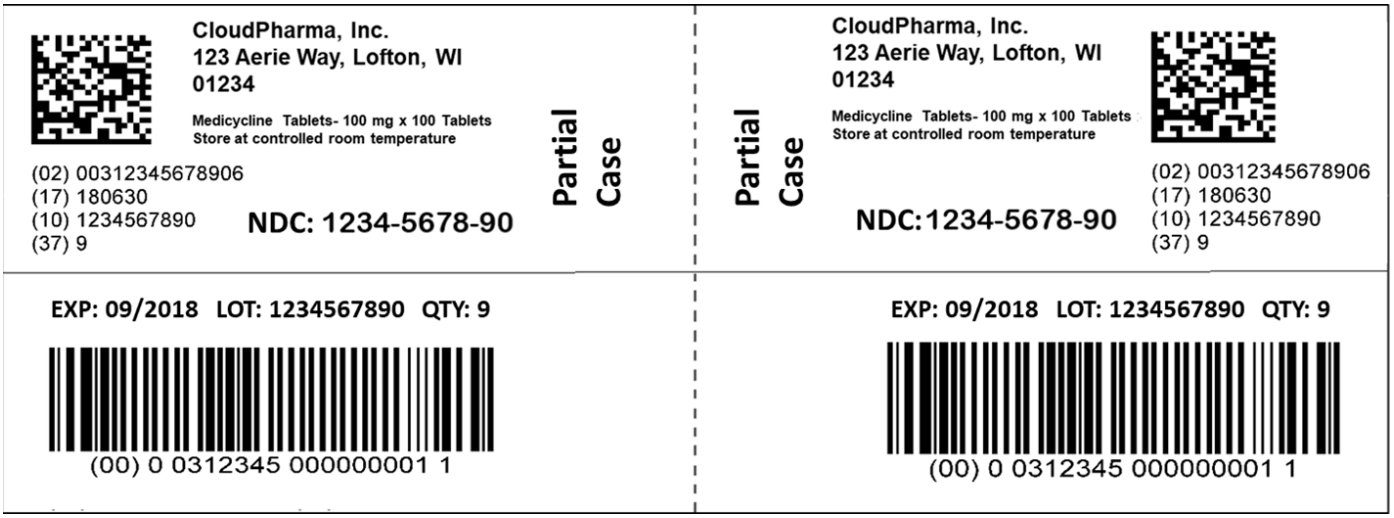


Figure 36

**Note that the example is not to scale.*

For a more basic label option, the next recommendation (partial homogenous case sold to a trading partner) also may be used.

Partial Homogeneous Case Sold to a Trading Partner[75]

For the labeling and serialization of these partial, homogeneous cases, these guidelines recommend including a GS1 Serial Shipping Container Code (SSCC) and the word "partial." It is recommended that partial case labels not include a secondary linear bar code, so the design looks distinct from that of a full homogeneous case. Quantity can be manually written in. Additionally, if you choose to include internal-use bar codes, they should be clearly labeled "for internal use" or bracketed and appropriately spaced from other bar codes so that it is distinguishable and separate. Putting them on the bottom of the bottle or at least opposite of each other is ideal, in addition to using a carrier that is not a GS1 bar code. See the following example:

Figure 37

**Note that some companies may print the NDC on package labels, either because they have an NDC number for the case or pallet or for commercial purposes.*

75. http://gs1.org/docs/barcodes/GS1_General_Specifications.pdf.

Non-Homogeneous/Mixed-Product Cases: Serialized Shipping Container Code (SSCC) Labeling

The DSCSA's requirements do not apply to labeling and serialization of a non-homogeneous or mixed case — though the statute would apply to the individual saleable units within the case, which would each have to bear the product identifier in a 2D Data Matrix. These guidelines recommend that there be no product identification labeling associated with mixed cases but that they are labeled with a logistics label — Serial Shipping Container Code (SSCC) — in accordance with GS1 standards.

The GS1 General Specifications[76] describe the SSCC label format. The relevant sections detail the structure and layout of GS1 logistics/SSCC labels. Emphasis is given to the basic requirements for practical application in an open trade environment. Primary topics include:

- The unambiguous identification of logistic units;
- The efficient presentation of text and machine-readable data;
- The information requirements of the key partners in the supply chain: suppliers, customers and carriers; and,
- Technical parameters to ensure systematic and stable interpretation of labels.

The GS1 General Specifications also say the label itself should measure not less than 4 inches wide, and in the U.S. pharmaceutical supply chain, it generally will be 6 inches tall. The building blocks are arranged to support three logically grouped information segments based on GS1 General Specifications and various trading partners' needs. These segments are stacked vertically and, from the top, include the following (generally in this order), as depicted in the following example:

- Carrier Segment:
    - Carrier identification
    - Ship-from address
    - Shipment number
    - Ship-to address
- Customer Segment:
    - Purchase order number
    - Case count
- Supplier Segment:
    - Serial Shipping Container Code (SSCC)

76. § 581(11),(12), 21 U.S.C. § 360eee(11),(12).

Each block has a title that appears in the upper-left corner, printed in uppercase characters. It contains a human-readable identification of the type of information in each field.

TITLE LINE: (Human-readable information)

Building block example for the serialized shipping container label

Any information encoded in a bar code should conform to GS1 system data structure requirements and use the GS1-128 symbology. Companies should follow the relevant GS1 standards, but due to the size of the label and space considerations, there may be exceptions in some situations. The data encoded in the bar code symbol should be represented in the appropriate HRI above the bar code. The human-readable characters are uppercase and usually left justified with the bar code, leaving room for the title line. AIs are considered part of the data and should be included in the human-readable format, separated from the rest of the data, within parentheses. Consult the GS1 General Specifications and GS1 Logistic Label Guideline for additional details.

The following diagram is an example of the HDA guideline-recommended SSCC label with each of its building blocks defined and described.

1. Ship-From Information
Enter the origin address
Rec'd Font Size 10-12pt; Area 1" x 1¾"

2. Ship-To Information
Enter the customer warehouse address
Rec'd Font Size 10-12pt; Area 1" x 2¼"

3. Ship-To Postal Code
Enter as shown, with bar code of zip code below
Rec'd Font Size 10-12pt; Area 1" x 2"

4. Shipper Information
Include four-digit SCAC code of carrier, route (opt), bill of lading or carrier/PRO number
Rec'd Font Size 10-12pt; Area 1" x 2"

5. PO Number
Enter the customer PO number with bar code of the number below
Rec'd Font Size 20-24pt; Area 1" x 4"

6. Expanded Supplier Namer
Enter the first seven characters of the supplier's name
Rec'd Font Size 36-40pt; Area 1" x 2¾"

7. Customer Warehouse ID
Enter the four-digit customer warehouse number (first four digits from PO number)
Rec'd Font Size 36-40pt; Area 1" x 1¼"

8. SSCC
Enter the SSCC Identifier with large bar code below
Rec'd Font Size 18-22pt; Area 2" x 4"

Figure 38

- **Carrier Identification:** This information is carrier assigned and for the internal use of the carrier. The carrier and the supplier will agree on the contents of this field and include the SCAC and perhaps the PRO number, if the necessary information can be provided to the labeler. This building block is specified to be 4 inches wide (the width of the label) and 1.5 inches high.
- **Ship-From Address:** This is the human-readable address of the origination point of shipment. This building block is specified to be 1.33 inches wide and 0.75 inches high.
- **Shipment Number:** The bill of lading number is in this field. It can be bar coded if the involved parties agree to accept an existing GS1 Application Identifier specifically for this purpose. This building block is 2.67 inches wide and 0.75 inches high.
- **Ship-To Address:** This is the human-readable address of the shipping destination point. This building block is specified to be 4 inches wide and 1 inch high.
- **Purchase Order Number:** The customer purchase order number is in this field. It should be encoded in GS1-128 symbology using GS1 Application Identifier AI(400). This building block is 2.67 inches wide and 0.75 inches high.
- **Case Count:** This is the human-readable case count or number of cases in the shipment, typically expressed as "xx OF yy." This building block is specified to be 1.33 inches wide and 0.75 inches high.
- **Serial Shipping Container Code (SSCC):** The 18-digit GS1 SSCC number is in this field. It should be encoded in GS1-128 symbology using GS1 AI(00). This building block is 4 inches wide and 2 inches high.

Individual Shipping Cases and Pallets: Logistics/SSCC Label Placement

The logistics/SSCC label should be affixed to the long side of the shipping case, no closer than 1.25 inches (32 millimeters) from any package edge. Avoid placing the label toward the center of the sides of rectangular corrugated packages to prevent undue exposure and resultant abrasion damage.

For individual shipping cases up to 39 inches (1 meter) in height, the top and right edges of the label should be within 1.25 to 3 inches (32 to 76 millimeters) of the top edge and within 1.25 to 3 inches (32 to 76 millimeters) of the right edge of the long side of the package (preferably the same long side on which the HDA-recommended product identification case label is visible; see Figure 39A).

For individual shipping cases larger than 39 inches (1 meter) in height, place the label so the bottom edge of the label is within 30 to 33 inches (76.2 to 83.8 centimeters) of the natural bottom of the case and the right side of the label is within 1.25 to 3 inches (32 to 76 millimeters) of the right edge of the long side of the package (preferably the same long side on which the HDA-recommended product identification case label is visible; see Figure 39B).

GUIDELINE RECOMMENDATION

Depending on what type of system or camera companies are using, it may be challenging to read labels through shrink wrap unless the label is secured in a good position. **These guidelines recommend adding a label on the outside of the shrink wrap or using a stretch wrap. If that is not possible, making the label clearly visible from the top of the shrink wrap is advised.**

Multiple Data Carriers on Logistical Containers

If a trading partner applies two different labels for the same purpose (e.g., a SSCC encoded bar code label and a SSCC encoded in an RFID tag), the encoded SSCCs must be the same. There is no expectation for the serial reference within a SSCC to mirror the serial number(s) a part of product identification information encoded in a bar code label and/or RFID tag. A single container may have a product ID label and a label with a SSCC encoded. The identification keys encoded in these labels are intended for different purposes, so there is not inherent need for the serial number with the product ID to match the serial reference of the SSCC. This prevents ambiguity and confusion when the containers are read.

Furthermore, and most importantly, all serial numbers applied should appear in all electronic communications related to the shipment (ASN and/or EPCIS) so that when the recipient reads any one of the serial numbers, they can find the proper information about the contents of the container within the electronic communication.

Pallets and Unit Loads: Logistics/SSCC Label Placement

For pallets or unit loads up to 39 inches (1 meter) in height, the top of the label should be within 1.25 to 3 inches (32 to 76 millimeters) of the top edge of the pallet or unit load. Unit loads should have the label on a minimum of two adjacent sides (Figure 39C), although four sides are preferred.

For pallets or unit loads greater than 39 inches (1 meter) in height, place the label so the bottom edge of the label is within 30 to 33 inches (76.2 to 83.8 centimeters) of the natural bottom of the pallet or unit load. Pallets should be loaded with heavier items on the bottom. The GS1 General Specifications recommend using 40 by 48 heat-treated pallets. If pallets are mixed, they should be identified as such. Labels should not be obscured by strapping or banding.

Depending on what type of system or camera companies are using, it may be challenging to read labels through shrink wrap unless the label is secured in a good position. These guidelines recommend adding a label on the outside of the shrink wrap or using a stretch wrap. If that is not possible, making the label clearly visible from the top of the shrink wrap is advised.

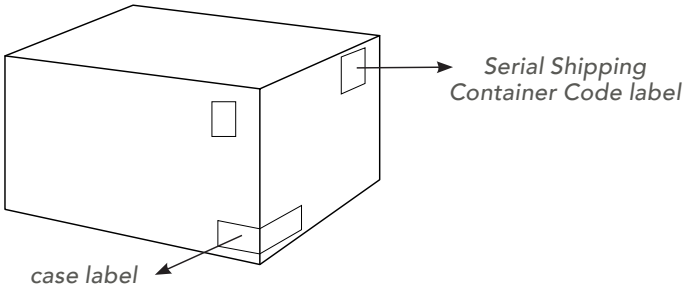


Figure 39A

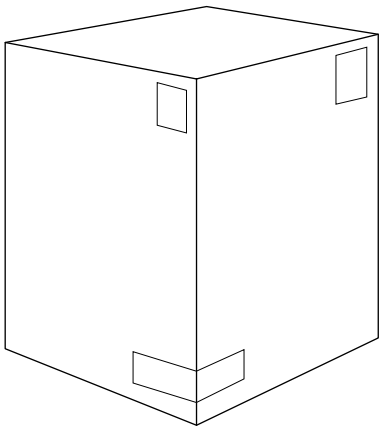


Figure 39B

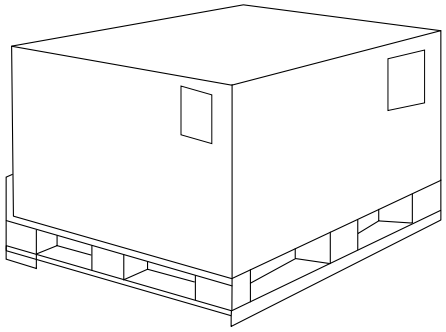


Figure 39C

GUIDELINE RECOMMENDATION

These guidelines encourage the use of the GS1 Logistics Label Guideline for using the SSCC — except the deviations noted in this document.

Also recommended is bar coding the narrow side (or front) of the case (one side minimum) for single cases at receiving, on conveyors and shelf storage.

SPECIFYING SYMBOL SIZE: X-DIMENSION VS. MAGNIFICATION

Among all GS1 and HIBCC symbologies, when referring to symbol size, the term "magnification" or "magnification factor" is used only with respect to the UPC symbology (and, in the past, ITF-14, the use of which is no longer endorsed by the current HDA guidelines). Some bar code symbol generation software incorrectly refers to "magnification" when specifying the size or narrow element width ("X dimension" of other symbologies).

When referring to size of a bar code symbol's narrow element width, the correct term to use is X-dimension, which can be equated to a magnification only in EAN/UPC symbology. Specifically, the UPC (or EAN) "nominal" size symbol of 100 percent magnification has an X-dimension of 13 mils (0.013 inches) or 330 microns for metric-based systems.

In EAN/UPC this nominal X-dimension is specified in the symbology standard and provides a fixed dimensional reference for the relative reference of magnification. No such nominal X-dimension is specified for any other GS1 or HIBCC symbology that is currently endorsed by the HDA Bar Code Task Force. Therefore, any use of a reference to magnification in bar code symbol generation software for any other symbology must be in relation to some arbitrary X-dimension selected by the software provider. This practice causes considerable confusion and should be avoided.

Fortunately, most of this type of software also allows the user to specify symbol size using X-dimension. Users should choose this method and ignore any derived expression of magnification, which is not a recognized or appropriate term for any symbology other than UPC (or EAN).

NON-PHARMACEUTICAL PRODUCTS: UPC NUMBERING SCHEME, UPC SYMBOLOGY

The DSCSA's product identifier and bar coding labeling requirements only apply to prescription drugs in a finished dosage form for administration to a human patient without further manufacturing.[77] The NDC drug listing requirements apply to all drugs.[78]

Medical products that are not drugs (and so do not bear an NDC) and NHRIC items coded with the UPC numbering system and UPC symbology can have a variable-length U.P.C Company Prefix beginning with "0," "1," "6," "7," "8" or "9," followed by the manufacturer-assigned item number and the calculated mod-10 check digit. Some OTC products and most general merchandise products have a UPC bar code symbol with the traditional "1-5-5-1" UPC human-readable format, regardless of the relative length of the respective U.P.C Company Prefix and item code. However, the arrangement of the human-readable numbers does not imply any length of a UPC Company Prefix or manufacturer-assigned product identification code. Once combined, the complete GTIN-12 data structure comprises a globally unique pointer to a database record. Once constructed by the labeler, the GTIN cannot be parsed or broken down into parts since the length of the UPC Company Prefix generally is not known.

77. The *Federal Register* notice amending the NDC and bar code rules and publishing these rules in final is available at https://www.federalregister.gov/documents/2016/08/31/2016-20471/requirements-for-foreign-and-domestic-establishment-registration-and-listing-for-human-drugs.

78. The NDC rule, as amended, is available at https://www.law.cornell.edu/cfr/text/21/part-207 (retrieved on May 3, 2017); see 21 C.F.R. § 207.41.

UPC Company Prefix	GS1 Company Prefix
614141 850006000	0 614141 0 850006000

Figure 40

The GS1 system distinguishes between a UPC Company Prefix and a GS1 Company Prefix. The UPC Company Prefix is that number to which a company adds its item identification to generate a GTIN-12 data structure and the UPC symbol. The GS1 Company Prefix is one digit longer and, in North America, includes a leading zero before the UPC Company Prefix.

TECHNOLOGY CONSIDERATIONS

Bar Code Scanners

With the DSCSA requirement that manufacturers affix product identifiers with a 2D Data Matrix to products, the use of GS1 DataMatrix 2D symbology is increasing rapidly throughout the global pharmaceutical supply chain. Reading 2D Data Matrix requires a 2D imager (scanner). Linear laser or CCD cannot read Data Matrix codes; however, 2D imaging scanners can read both linear and 2D bar codes such as Data Matrix or Aztec Code or QR Code. Since Data Matrix and other 2D codes are becoming popular, the guidelines recommend upgrading to imaging scanners capable of reading Data Matrix and linear codes whenever auto-ID procurement needs are under consideration. As the cost of 2D imagers has decreased in recent years, the price differential between linear scanners and 2D imagers is less likely to be a barrier to implementation.

From the manufacturer's packaging line to the receiving dock, the hospital supply room to the patient, 2D bar codes are becoming increasingly prevalent and eventually will be mandatory for DSCSA compliance once all packages bear a product identifier encoded in a 2D Data Matrix.

GUIDELINE RECOMMENDATION

These guidelines recommend investing in and/or upgrading to imaging scanners capable of reading Data Matrix and linear codes whenever auto-IDID procurement needs are under consideration. When upgrading or purchasing new bar code scanners, reference the "GS1 US — Healthcare Bar Code Scanner Acquisition Criteria."

APPLICATION SOFTWARE DESIGN ISSUES: ISO/IEC SYMBOLOGY IDENTIFIERS

The GS1 General Specifications, other GS1 specifications and application guidelines and many of the related bar code symbology specifications clearly stipulate that efficient data collection in the global GS1 system depends on the use of standardized ISO/IEC Symbology Identifiers in conjunction with GS1 AIs. To understand the implications of this critical requirement, one first must understand the purpose and role of these two critical "metadata" elements.

The ISO/IEC Symbology Identifier is a unique, globally standardized three-character code that unambiguously identifies a specific bar code symbology. This element of metadata is not encoded in the bar code but rather is provided by the scanner, which has a programmable setting to transmit these three characters as a prefix to the data encoded in the symbol. For this reason, it is critical to ensure that the scanners one intends to purchase fully support this long-established, industry-standard feature (most do).

Knowing which symbology has been scanned is a critical piece of information to have in any situation, but is most critical in an open, global supply chain where items from a wide variety of sources bar coded according to different standards are commonplace. Such is the nature of the healthcare supply chain.

Using the ISO/IEC Symbology Identifier, suitably programmed data-collection systems from the manufacturer's shipping dock through the distribution channel, right down to the point of care, can perform their initial input data string evaluation and choose the best next step in data processing for their needs. For example, knowing if you scanned a UPC or GS1 DataBar or GS1-128 symbol, you could use the GS1 format data processing according to AI rules. Thereafter, the system determines the length of the data string and begins to evaluate it for the presence of AIs and, if necessary, to break it into separate data elements (such as GTIN, quantity, expiration date, lot number, serial number, etc.) for you.

GS1-128, GS1 DataBar, GS1 DataBar/Composite and GS1 DataMatrix all encode AIs, whereas UPC, EAN and ITF-14 never do. These latter three data carriers can only encode a GTIN (12-, 13- or 14-digit formats, respectively), so knowing the symbology and the string length is sufficient to understand how to process the data.

By the same token, if you know from looking at the ISO/IEC Symbology Identifier that you have scanned a Code 39 symbol or a "plain" Code 128 symbol (as opposed to a GS1-128 symbol) and the symbol starts with the plus character ("+"), then you know to use HIBCC format data processing.

The rules for such "front-end" logic are somewhat complex, depending on the diversity of data elements encountered at any point in the supply chain. Expert resources should be consulted for further details.

SCANNER AND DATA-COLLECTION HARDWARE ISSUES

Several scanner and data-collection hardware issues also should be taken into consideration when designing and implementing any bar code scanning solution. A few important considerations include: The scanner form-factor (handheld, presentation, fixed-mount); its working range and focal length for a given symbol X-dimension; optical properties (laser or imager; linear or 2D); and ergonomic design. In addition, many of today's scanners offer wireless Bluetooth® connectivity along with the traditional cabled connections through RS-232, keyboard wedge interface or, more typically today, USB. As already pointed out, a scanner must be capable of fully supporting the transmission of ISO/IEC Symbology Identifiers as a prefix to the scanned data. There are more than 100 handheld and small form-factor scanner models from a wide range of manufacturers that scan traditional linear, GS1 DataBar, GS1 DataBar/Composite and 2D Data Matrix symbols, in some combination depending on the model.

Beyond scanners are portable data-collection terminals (PDTs), most of which would normally be equipped with an integrated scanner. This is helpful for point-of-care use, but throughout the healthcare supply chain. Such PDTs come in a vast array of form factors with widely different feature sets, from small handheld units such as the personal digital assistants (PDAs) to wireless vehicle-mounted devices on fork-lift trucks in warehouses.

In addition to the scanner considerations already mentioned above, the evaluation of PDTs also must include their operating system, display capabilities, keypad configuration, and battery life, among others.

HDA BAR CODE TASK FORCE RECOMMENDATIONS

- Obtain a GS1 Global Company Prefix and correctly embed the NDC within the GTIN. A unique GTIN is necessary for each packaging level and configuration.
- HDA does not support the use of "00" as the day of the month and recommends using a specific day of the month such as "31" so that the expiration date encoded exactly matches electronic data passed between trading partners.
- AI(22) and AI(30) are no longer recommended. During this transition period, if AI(30) continues to be used in the secondary linear bar code, note that inclusion in the GS1 DataMatrix symbol of the explicit case quantity represented by AI(30) is not in accordance with the GS1 General Specifications and GS1 standards no longer permit it.
- In accordance with the DSCSA, these guidelines recommend encoding:
    - The NDC [AI(01) + 14 digit GTIN], unit-level serial number [AI(21) + 1-20 digit serial number, expiration date [AI(17)+ 6-digit date in YYMMDD format] and lot number [AI(10) + 1-20 digit alphanumeric lot number] using the GS1 DataMatrix data carrier.
    - A valid day (NOT "00") should be used in the AI (17) six-digit date so that the expiration date encoded exactly matches electronic data passed between trading partners.Information and summaries of these GS1 AIs [AI(01), AI(21), AI(17), AI(10)] are available here
- These guidelines recommend using UPC-A in retail settings where scanning systems tend to be older and in the process of being upgraded. In the case of space constraints truncated or reduced UPC-A is preferred. Reduced UPC-A generally is easier to read by the supply chain. GS1 DataBar as an alternative data is acceptable in hospital and institutional settings.
- For inner packs, labeling is not required. However, if a trading partner opts to do so, it is recommended to include at minimum a 2D Data Matrix, encoded with a unique GTIN, and corresponding human-readable format. Also, if using shrink wrap include a label on the outside for easy readability.
- For homogeneous cases, use a corner wrap label for DSCSA serialization compliant labeling, or at a minimum, labels on two adjacent sides. Note that the 2D bar codes are placed on the outer edges, away from the corners of the label.
- For partial cases, note that there are two distinct label options included, depending on if a partial case is internally transferred or sold to a trading partner. For partial cases internally transferred, labeling is up to the discretion of the manufacturer. These guidelines provide an example for those who wish to include a 2D Data Matrix, including AI(02) and (37). For those sold to a trading partner, including the word "partial" and a SSCC is recommended.
- Non-homogeneous or mixed-product cases should always include a SSCC.

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