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Guidelines for Bar Coding in the Pharmaceutical Supply Chain

HDA

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HDA GUIDELINES FOR BAR CODING IN THE PHARMACEUTICAL SUPPLY CHAIN

HDA would like to thank **Excellis Health Solutions LLC** for their barcoding and serialization expertise in supporting the Bar Code Task Force development of the *HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain*. Excellis Health Solutions is a global provider of strategy and implementation consulting services within the life sciences and healthcare industries. Excellis provides deep subject matter expertise in compliance with global product traceability regulations, GS1 Standards and pharmaceutical/medical device supply chain systems implementation. Services include strategy, project/program management, comprehensive validation, change management, quality and regulatory compliance, managed services administration, software release management, subject matter support, global GS1/serialization/track-and-trace support; as well as education and training and systems integration. As a GS1 Solution Partner, Excellis Health Solutions has certified subject matter experts with GS1 Standards Professional Designation and GS1 Standards for UDI.

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The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 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 non-profit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.
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TABLE OF CONTENTS

SUMMARY OF REVISIONS

Below is a list of significant changes from the 2011 ***HDMA Guidelines for Bar Coding in the Pharmaceutical Supply Chain***. The following changes are presented in further detail throughout the document:

- Inclusion of an overview and history of the Drug Supply Chain Security Act (DSCSA);
- Removal of AI(30) from the GS1 DataMatrix;
- Clarification of expiration date;
- Requirements for four data elements of a product identifier mandated by DSCSA;
- Recommendations for encoded elements, order of encoding and human-readable interpretation (HRI);
- Inner-pack recommendations and specifications;
- Corner-wrap recommendation and specifications;
- Partial/mixed case recommendations;
- Recommendation that "N" is no longer printed on labels for packaging greater than the saleable unit;
- Recommendation to use UPC-A to comply with the bar code rule;
- Inclusion of updated links to the 2017 GS1 General Specification; and,
- Inclusion of updated images and figures to display current recommendations, including a summary specifications table for serialized and non-serialized products.

INTRODUCTION

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

The 2017 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 guidance on bar coding, *Numerical and Automatic Identification of Drug Products*, as a guideline 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 most recently in 2011; HDA also published two "Quick Start Guidelines" for bar coding in the pharmaceutical supply chain in 2014 and 2016. These guidelines supersede the 2016"Quick Start Guideline" and other previous versions.

The most important change necessitating an update to the 2011 *HDMA Guidelines for Bar Coding in the Pharmaceutical Supply Chain* is 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.

This revision serves as an industry-wide voluntary guideline on the use of globally accepted GS1 system data structures and symbologies to convey the DSCSA-required National Drug Code (NDC), a unique serial number, expiration date and lot number, as well as optional quantity information. The information advises on the printing of this two-dimensional (2D) Data Matrix bar code on pharmaceutical products at, above and below the trade item level (the smallest unit of product that can be sold from inventory or purchased or added to inventory). In addition, this revision provides detailed guidance on shipping case bar code label format, marking and placement, and 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.

This 2017 edition of the *HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain* reflects supply chain practices on bar coding as the industry works to meet the DSCSA requirements to transact only in serialized products that include a standardized graphic, in both a human-readable format and on a machine-readable data carrier, that conforms to international standards. These revisions include changes in terminology and updated and expanded content, including additional information on GS1 standards; the Drug Supply Chain Security Act; and differentiated label examples for serialized and non-serialized product.

Every effort has been made to maintain the solid, 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.

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1 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.

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 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 in the 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 that 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]

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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).

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] that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters."[10]

This requirement for manufacturers 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 is to go into effect on November 27, 2017; the compliance date is one year later, November 27, 2018, for repackagers.[11] On July 3, 2017, 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 currently remains November 27, 2018. As of the release of these guidelines this "Product Identifier Compliance Policy" was still in draft form and could change. Stakeholders are advised to closely review the "Product Identifier Compliance Policy" to determine effective dates, applicability to serialization and compliance status. Stakeholders also need to stay informed on further FDA announcements that could impact timing of and compliance with DSCSA requirements.

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,[13] requires an encoded, standardized linear bar code containing the NDC number on human prescription drugs, biologics[14] 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 a minimum, the appropriate drug's NDC number in a linear bar code that meets European Article Number/Uniform Code Council (now GS1) or Health Industry Business Communications Council (HIBCC) standards or another standard or format that has been approved by FDA.[15]

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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 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).

14 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)].

15 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[16] and be surrounded by sufficient blank space so that it can be scanned correctly.[17] 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, if any, or be easily legible through the outside container or wrapper.[18]

The "FDA Bar Code Rule Decoded," published by the Association for Automatic Identification & Mobility (AIM), may be purchased through the AIM website.

GUIDELINE RECOMMENDATION

Pharmaceutical manufacturers have typically used UPC-A to comply with the bar code rule. 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, 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. The GS1 DataBar is less preferred based on current hardware and configuration within wholesale distribution and retail channels.

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

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

The FDA final guidance, "Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages"[19] (or "FDA SNI Guidance") was an initial step in FDA efforts to begin developing unique SNIs for prescription drug packages.[20] The guidance was published in 2010 and so predates the DSCSA. However, the guidance provides useful information concerning serialization of prescription drugs and it appears that FDA believes the guidance to be helpful in building the product identifiers required under the DSCSA.

In the "FDA SNI Guidance," the agency provides an example of an SNI that contains a 10-digit NDC as discussed at the beginning of this section and a unique serial number of up to 20 numeric or alphanumeric characters. The FDA 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.[21]

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16 21 C.F.R. § 201.25(c)(2).

17 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).

18 § 201(k), 21 U.S.C. § 321(k) (definition of "label").

19 "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. A guidance is not legally binding or enforceable but reflects FDA's current thinking on a topic.

20 The "FDA SNI Guidance" implemented a 2007 amendment to the FDC Act that began the process of serialization of prescription drugs that has since culminated in the 2013 passage and implementation of the DSCSA.

21 § 581(20), 21 U.S.C. § 581(20).

Of critical importance to DSCSA serialization, FDA notes that an sNDC may be presented within a Global Trade Item Number® or GTIN®, which can be serialized using the GS1 Application Identifier[22] AI(21) to create a serialized GTIN (sGTIN). In the "FDA SNI Guidance," the agency also recognized 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."

The "FDA SNI Guidance" has been helpful for supply chain trading partners working to implement the DSCSA who have been using it to create sGTINs and 2D bar codes using a GS1 DataMatrix as the carrier for the product identifiers.

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 individual unit and each homogeneous case. (As discussed above, though the product identifier requirements are effective for manufacturers on November 27, 2017, FDA has extended a one-year period of enforcement discretion during which it will not enforce the requirement.)

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.

22 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 http://www.gs1-128.info/application-identifiers/ (accessed May 17, 2017).

CONFIGURING THE NDC IN BAR CODES

Decoding the 10-Digit NDC

As discussed in the previous section, the NDC, by FDA regulation,[23] 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), and 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.[24]

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. That is, 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.

FDA revised the drug listing rule, 21 C.F.R. Part 207, in 2016, 81 Fed. Reg. 60169 (Aug. 31, 2016), which went into effect on November 29, 2016. Though there are many changes, FDA did not change the configuration of the NDC, nor how it is created and assigned.[25] Manufacturers and repackagers should carefully review the 2016 rule to see if there are any changes relevant to their NDC assignment and updating activities.

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23 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).

24 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 (81 Fed. Reg. at 60187). It is likely that FDA would only be able to undertake such a significant change in consultation with all stakeholders and after public notice and opportunity for comment.

25 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).

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.[26]

Each registrant must list with FDA, by NDC number, each drug that it manufactures, repacks, relabels or salvages for commercial distribution.[27] Commercial distribution refers to any distribution of a human drug with the exception of investigational uses and internal or interplant transfer between registered establishments under common ownership and control.[28] Each domestic registrant must list each such drug with FDA regardless of whether the drug enters interstate commerce.[29]

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. However, 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 new FDA NDC rule updates 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.[30] Any new NDC number or change to an existing one should be communicated to FDA as required by regulation. Changes should also be clearly and promptly communicated throughout the supply channel, to trading partners and to compendia database providers (such as First Databank, Medi-Span, Micromedex, etc.) so that the new numbers are included in the drug files made available by these clinical support vendors.

FDA's "Guidance for Industry, Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing,"[31] 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 never encoded in the linear bar code, 2D Data Matrix or any other standardized data structures.

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26 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).

27 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).

28 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).

29 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).

30 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).

31 https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf (retrieved on May 3, 2017).

Importance of NDC Format

There is an important and prevalent practice in certain segments of the pharmaceutical industry in which 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 eventually 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 re-formatting 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); and 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	NCPDP "5-4-2"
10-digit format	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

The NCPDP representation of the FDA-prescribed 10-digit NDC is **not** 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 DSCSA.[32] 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.

32 21 C.F.R. § 201.25 (bar code rule); § 581(2) (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 UPC numbering system, administered by GS1 US, is an all-numeric, 12-digit, fixed-length numbering system incorporating the UPC symbology. The UPC 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 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 includes 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. The item identification "key" within the global GS1 system is referred to as the Global Trade Item Number or GTIN. 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.

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 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 this 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://www.gs1us.org/upcs-barcodes-prefixes/get-started-guide/1-get-a-gs1-us-issued-company-prefix.

THE PRODUCT IDENTIFIER

As discussed previously, the DSCSA requires that by November 27, 2017,[33] manufacturers 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.[34] A "package" [35] 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.

UNDER THE DSCSA

Product Identifier = [SNI] + product expiration date + product lot number

NDC/GTIN + product's unique serial number[36]

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[37] that must conform to the standards developed by a widely recognized international standards development organization.[38] The product identifier must also be affixed to or imprinted on each homogeneous case in **either** a linear or 2D Data Matrix bar code.[39]

These guidelines address how to build a GTIN with the embedded NDC, how to serialize that GTIN, and how to add the product lot number and product expiration to create a DSCSA-compliant product identifier, using GS1 standards and 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 100 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.

GUIDELINE RECOMMENDATION

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 in the GS1 General Specification.

33 As discussed previously, on July 3, 2017, FDA released a draft guidance 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. See the "Product Identifier Compliance Policy," https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf (retrieved July 11, 2017). The "Product Identifier Compliance Policy" is a draft and its non-enforcement provisions and DSCSA interpretations could change.

34 § 582(b)(2)(A), § 21 U.S.C. § 360eee-1(b)(2)(A).

35 § 581(11), § 21 U.S.C. § 360eee(11).

36 § 581(14), 21 U.S.C. § 360eee(14).

37 § 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)].

38 § 581(14), 21 U.S.C. § 360eee(14).

39 § 582(a)(9)(A)(ii), 21 U.S.C. § 360eee-1(a)(9)(A)(ii).

Building the GTIN

The 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[40]) by GTIN using the standardized GS1 system bar code format that incorporates the product's NDC. The support for this approach is found, as discussed in this section, in FDA's explicit recognition that a serialized NDC can be represented in a GTIN in accordance with GS1 global standards, to which, in turn, a unique serial number can be added. Most manufacturers and labelers have begun 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 whenever 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.
- Are used for any item that may be priced, ordered or invoiced at any point in the supply chain.[41]
- Unlike the NDC, are valid and unique globally.
- Where manufacturers or repackagers have multiple packs of the same product for different markets (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 zeroes. This lowest level of packaging must not be given an indicator digit (other than leading zeroes) because GS1 rules will not permit two different GTINs on the same package.
- 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.

40 *See* definition of "package," § 581(11), 21 U.S.C. § 360eee(11).
41 https://www.gs1.org/sites/default/files/docs/barcodes/GS1_GTIN_Management_Standard.pdf.

As discussed inthe previous section, the "Company Prefix" is assigned by GS1; in the U.S., the 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 GS1 prefix and 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

From the NDC examples:

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

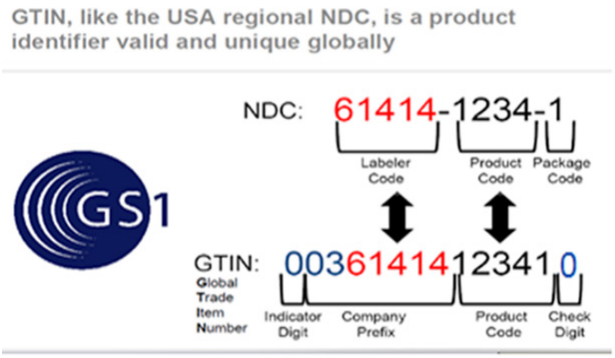
4-4-2 Format: NDC 0001-4096-60

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

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

GS1 rules outline that HRI 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:



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.

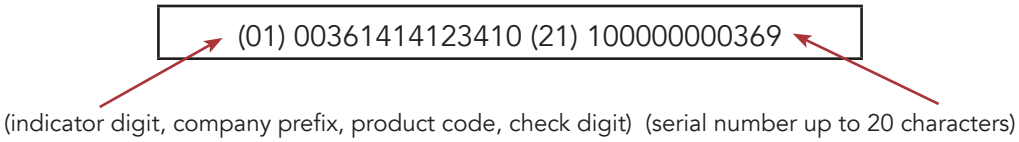
Also, as discussed in the section outlining FDA's bar coding requirements, a new FDA drug listing rule went into effect on November 29, 2016. This new rule amended when changes to a product require the manufacturer or labeler to assign a new NDC number.[42] A new NDC number will trigger changing the GTIN as well.

42 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[43] (or homogeneous case[44]). 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.[45] As discussed in this section, FDA provided advice on how to create a unique SNI in its final guidance, "Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages."[46] FDA recognizes (and these guidelines recommend) that an NDC be presented within a GTIN AI(01) followed by a 20-character unique identifier in GS1 AI(21) format to create a serialized GTIN (sGTIN).

To serialize the previous GTIN example:



GTIN Number [GS1 AI(01)]: 00361414123410
Serial Number [GS1 AI(21)]: 100000000369

It may be helpful 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, including, but not limited to, the possibility of erroneous and unexpected truncation of leading zeros because of numeric field formatting.

Expiration Date

The DSCSA requires, in addition to the SNI built above, inclusion of the product's expiration date in the product identifier. These guidelines recommend the GS1 AI(17) + 6-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). 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).

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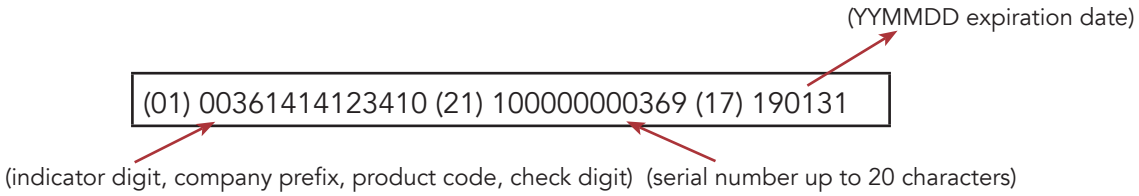
43 A "package" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product" [§ 581(11)(A), 21 U.S.C. § 360eee(11)(A)].

44 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)].

45 § 581(20), 21 U.S.C. § 360eee(20).

46 https://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm.

To continue the example to build a product identifier:



GTIN Number [GS1 AI(01)]: 00361414123410
Serial Number [GS1 AI(21)]: 100000000369
Expiration Date [GS1 AI(17)]: 190131

GS1 General Specifications clearly differentiate between HRI and non-HRI text. 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, when represented as non-HRI text, always be represented in its complete "CCYY" (Century, Century, Year, Year) four-digit format.

Expiration Date	Non-HRI Text	YYMMDD Encodation
January 31, 2018	JAN 31, 2018	180131
January 31, 2018	31 JAN 2018	180131
December 2018	DEC 2018	181231
December 2018	12/2018	181231

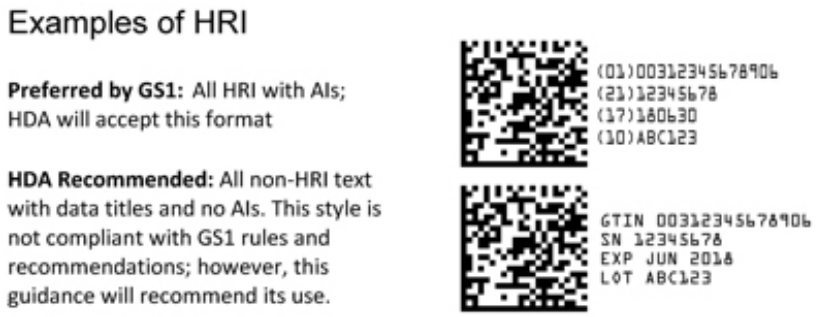
In both the first and second formats, the human-readable expiration date is transcribed into an equivalent bar code data format, as illustrated by the examples in the preceding table. Although the human-readable and the encoded bar code formats are not identical, they are exactly equivalent and the information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



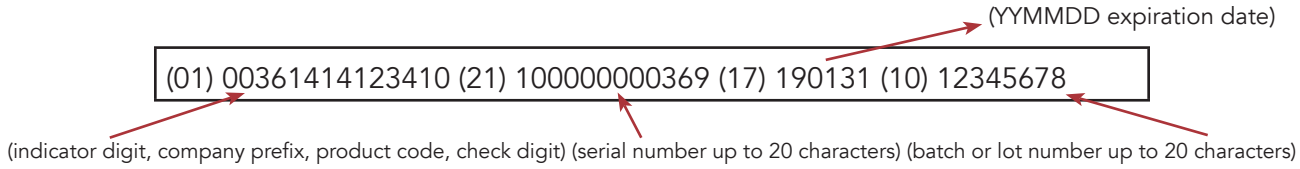
The graphic above represents examples of HRI and non-HRI text as would be represented on a unit-of-sale label. Whereas the GS1 preferred HRI is acceptable (use of AIs within parentheses), the HDA recommendation is the use of non-HRI text with data titles and no AIs.

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:

Lot Number

The DSCSA requires inclusion of the product's lot number in the product identifier. These guidelines recommend the GS1 AI(10) with one to 20 alphanumeric characters representing the batch or lot number.

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



GTIN Number [GS1 AI(01)]:	00361414123410
Serial Number [GS1 AI(21)]:	100000000369
Expiration Date [GS1 AI(17)]:	190131
Batch or Lot Number [GS1 AI(10)]:	12345678

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 often 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.

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 some 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 the recommended practice.

TWO-DIMENSIONAL (2D) BAR CODE

The DSCSA requires that 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.[47]

These guidelines recommend that the product identifier being encoded in the Data Matrix, including the GS1 system, be collectively referred to as the GS1 DataMatrix.

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

47 § 582(a)(9)(A), 21 U.S.C. § 360eee-1(a)(9)(A).

for Automatic Identification and Mobility (AIM) and introduced into the public domain (hereafter known as ISO/IEC DataMatrix). 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. ISO/IEC Data Matrix also has the capability of encoding the Electronic Product Code (EPC), a potentially valuable feature that could allow a GS1 DataMatrix symbol to serve as a redundant data carrier for RFID-enabled EPC applications. In 2004, FDA announced it would exercise enforcement discretion to permit supply chain stakeholders to pilot RFID programs and relieved participants, for a time, from certain requirements of the FDC Act. That enforcement discretion expired in 2014.[48] Until FDA provides a revised position of RFID use, these guidelines will not provide recommendations for RFID use.

In an ISO/IEC Data Matrix, the outer perimeter of the code is used to establish the bounds and to determine the 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.

Using the grid pattern established from the finder pattern and the clock track, a Data Matrix scanner looks to determine 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 black or white. The symbol can be printed via laser engraving, laser ablation, ink jet, hot foil stamping and thermal transfer as well as by traditional wet ink processes — another key benefit. 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.

48 CPG Sec. 400.210, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs, available at https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074357.htm (retrieved July 15, 2017).

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

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

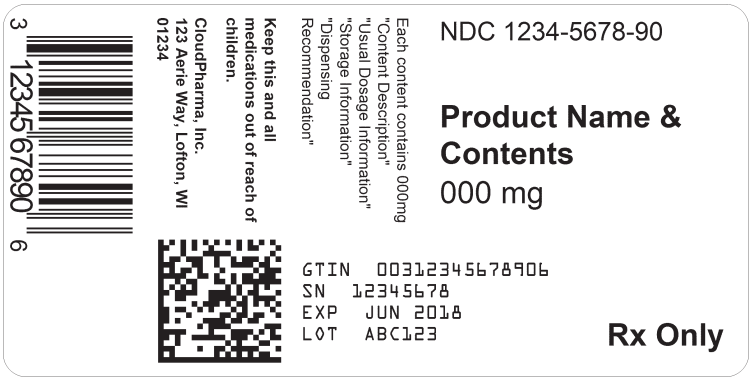
The GS1 DataMatrix should include the GTIN AI(01) + the serial number AI(21) + the expiration date AI(17) + the lot number AI(10) to create the DSCSA-compliant product identifier encoded in a 2D Data Matrix bar code.

The encoded data should appear as:

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

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.) The second FNC1 encoded as the character Group Separator, and often denoted by the convention "<GS>" or "GS," is used to terminate the variable length serial number prior to starting the next AI.

Since the lot number is the last data element encoded in the bar code, it is unnecessary to terminate this variable-length field using FNC1. The parentheses are not encoded in the bar code — they are only shown in a human-readable format. (Note: This sequence of data elements deviates from 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.



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

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

Note: There are no parentheses encoded in the bar code. The parentheses are only in the human-readable interpretation for readability purposes.

Below is an example of same label with GTIN eliminated from the human-readable text to save space (the GTIN HRI already exists on this label as associated with the UPC-A linear barcode).

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

Whenever serial numbers are affixed to saleable units/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, 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.

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.

Electronic Product Code Information Services (EPCIS)

The innovation broadly referred to as EPCIS (previously EPC) was first developed at the Massachusetts Institute of Technology's Auto-ID Center and is now housed within GS1, where the concept is being commercialized into an industry-driven standard by EPCglobal, Inc. The EPCIS itself is simply a data structure developed by industry participants at EPCglobal, where the EPCIS is being standardized to allow for the unique, serialized identification of single items. EPCglobal is attempting to build a communications network to facilitate the exchange of EPCIS data, which will drive supply chain applications, trading partner collaboration and more effective and efficient business decisions. The EPCIS network uses RFID as a key component of its facilitating technology, with EPCIS numbers encoded on RFID tags and wirelessly transmitted to RFID readers, which provide a gateway to the EPCIS network for the EPCIS data. For more information on the EPCIS, and to get involved in developing the EPCIS network standard, visit the GS1 US website.

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 (ASN or EPCIS events, 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.[49] Additionally, FDA's bar code rule, 21 C.F.R. § 201.25,[50] has long required certain drug products to bear an encoded, standardized linear bar code containing the NDC number.[51] The bar code must contain, at a minimum, the product's NDC in a format that meets GS1 or HIBCC standards, or such other standards that FDA might set.[52]

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49 § 582(a)(9)(A)(ii), 21 U.S.C. § 360eee-1(a)(9)(A)(ii).

50 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).

51 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)].

52 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).

As explained in "Building the GTIN," found 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, Version 17, Figure 5.2.4.6 – 2 for detailed dimensions associated with the formats shown below.

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.

BAR CODES ON VERY SMALL PACKAGING CONFIGURATIONS

Products Intended for Individual Resale

As discussed previously, 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 FDA for packages that are too small to accommodate the required information.[53] 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.

53 § 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.

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 2D Data Matrix product identifier as required under the DSCSA.[54]

However, FDA's bar code rule, 21 C.F.R. § 201.25, requires that all 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. Further, under the NDC rule, each registrant must list and obtain a unique NDC number for each drug that it manufactures, repacks, relabels or salvages for commercial distribution.[55] The linear bar code must include the drug's unique NDC, at a minimum. 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 FDA.[56] The 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 virtually every bar code scanner can read it. Methods of representing a linear bar code on very small packages are discussed in the next section.

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 for some older scanning systems to read these bar codes. This limitation 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 UPC-A generally tends to be more easily read than a truncated UPC-A. (Note: 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.

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54 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).

55 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).

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

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.

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, although not with GS1 Standards.57

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; note that the layout below is only one potential variation.)

57 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. 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).

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.

GTIN 20312345678900
SN 12345678
EXP JUN 2018
LOT ABC123

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.[58]

For bar code marking on cases, the industry traditionally has followed the guidelines set forth by GS1 specifying the GTIN-14 data structure 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 14-digit GTIN 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 Data Matrix 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.
- The primary homogeneous case GS1-128 bar code (bottom bar code) encodes the GTIN and the case serial number. These guidelines suggest that encoded data in the case primary GS1-128 linear bar code should appear as: <FNC1> + AI(01) + GTIN + AI(21) + Serial Number.

58 § 582(a)(9)(A), 21 U.S.C. § 360eee-1(a)(9)(A).

- The secondary case bar code (top bar code) encodes the expiration date, lot number and (optionally) quantity. 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, including:

- 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 encoded in GTIN-14 format plus concatenated case serial number in GS1-128 bar code with appropriate HRI per GS1 specifications; and,

8. NDC number encoded in GTIN-14 format, 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.

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

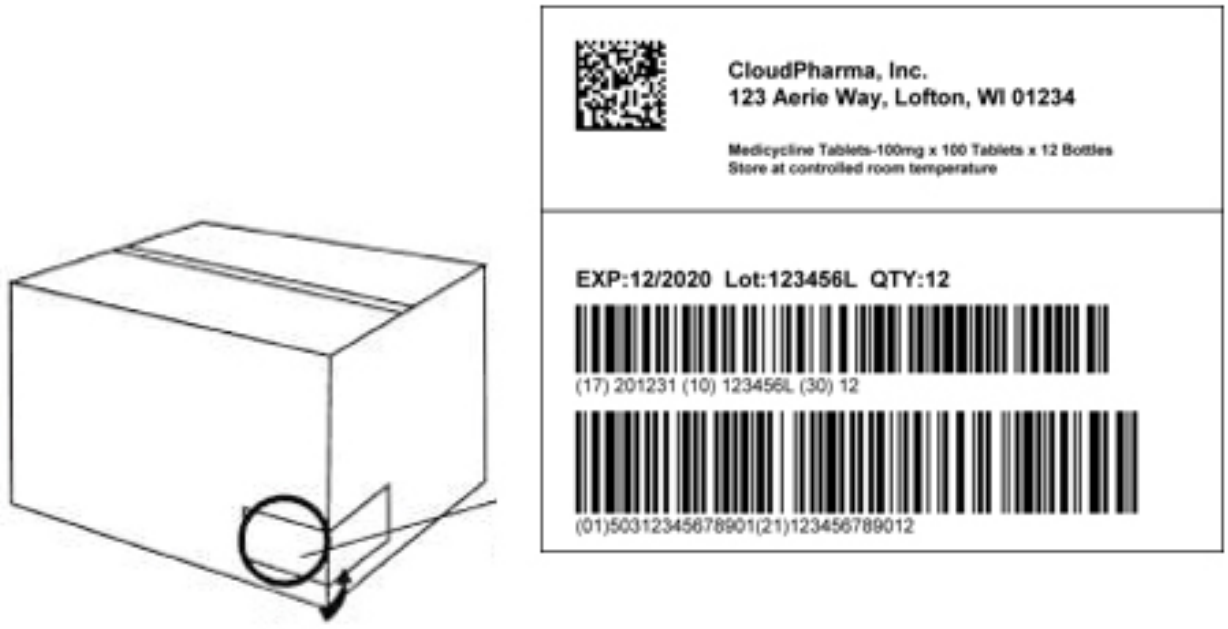
GUIDELINE RECOMMENDATION

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 case label samples below.

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.

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 at 0.75 inch from the shared corner and 1.25 inches from the bottom of the case.



Pharmaceutical distributors receive inquires regularly from their customers asking what company is 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.

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.

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.

HDA Shipping Case Product Identification Label: Summary Specifications

In Table 1, 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.

2017 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)	**GS1-128** (incl. FNC1 where req'd)
	Secondary:	**GS1-128** (incl. FNC1 where req'd)	**GS1-128** (incl. FNC1 where req'd)
	(2D) Prim + Exp & Lot:	**GS1 DataMatrix** (incl. FNC1 where req'd)	**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.)***	**16.7-30.0 mils (0.0167-0.0300 in.)***
	Minimum:	13.3 mils (0.0133 in.)*	13.3 mils (0.0133 in.)*
		*Use largest X-dim that will fit on the label	*Use largest X-dim that will fit on the label
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.)**	**30.0 mils (0.0300 in.)**
	Minimum:	30.0 mils (0.0300 in.)	30.0 mils (0.0300 in.)
Bar Code Quiet Zones - MINIMUM Width	GS1-128	10X (10 times X-dim; 0.20" min. recommended)	10X (10 times X-dim; 0.20" min. recommended)
	GS1 DataMatrix	3X (3 times X-dim; 0.10" min. recommended)	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)	1.5/10/660 (per GS1 & ISO/IEC 15416)
	GS1 DataMatrix	1.5/20/660 (per GS1 & ISO/IEC 15415)	1.5/20/660 (per GS1 & ISO/IEC 15415)
Position of Bar Code Symbols on Label	(2D) Prim + Exp & Lot:	GS1 DataMatrix, the Upper Label Corner Farthest from the Case Corner Edge	GS1 DataMatrix, the Upper Label Corner Farthest from the Case Corner Edge
	Secondary:	GS1-128, Directly Above Primary Symbol	GS1-128, Directly Above Primary Symbol
	Primary:	GS1-128, Bottom of Label	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.)	None (though data is NOT IDENTICAL to Prim. & Sec.)
	Secondary:	Below GS1-128, 10 point (8 point min.)	Below GS1-128, 10 point (8 point min.)
	Primary:	Below GS1-128, 10 point (8 point min.)	Below GS1-128, 10 point (8 point min.)
Secondary Data DESC.	Secondary:	Above GS1-128, 12 point (10 point min.)	Above GS1-128, 12 point (10 point min.)
Printing Process and Substrate	All Labels	Thermal Transfer Pressure-sensitive Label	Thermal Transfer Pressure-sensitive Label
Label Skew	All Labels	+/- 2 Degrees from Horizontal** **Approx. 0.15 inch Across a 4" Wide Label	+/- 2 Degrees from Horizontal** **Approx. 0.15 inch Across a 4" Wide Label

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.

03 August 2017 Rev 1e

Product Identification Label Format 1 — Serialized Product

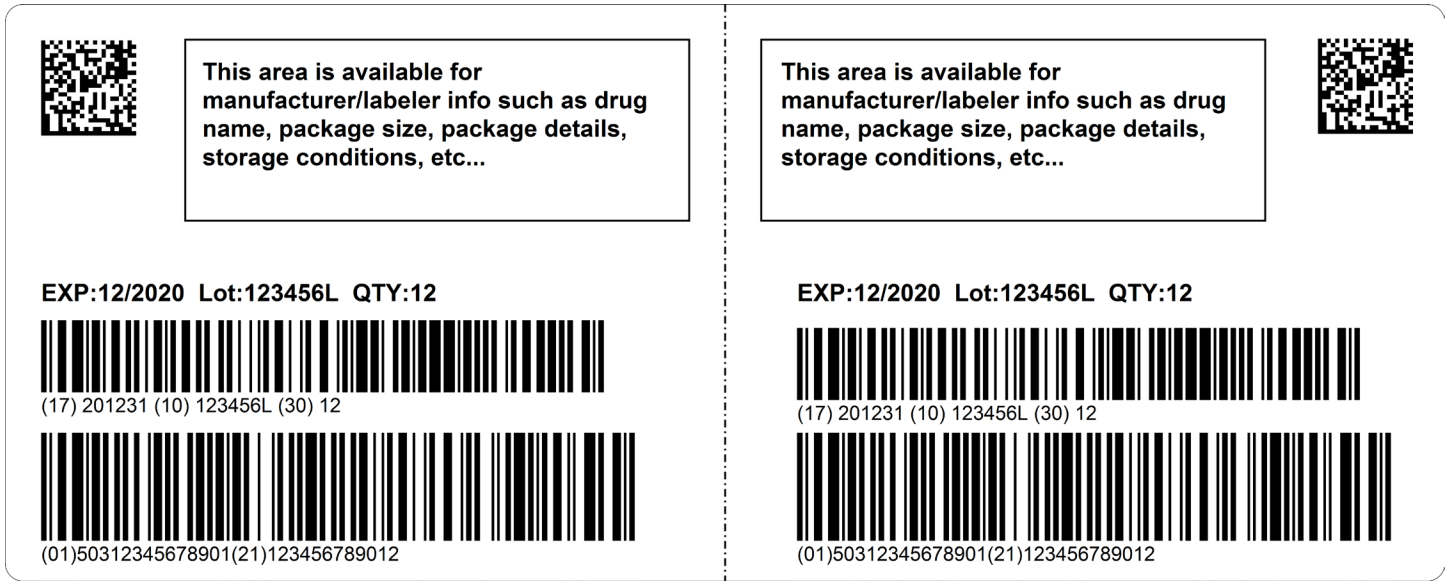
Label Format 1 — Serialized Product

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 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). 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.



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 will be automatically decoded, translated and transmitted by a scanner as <GS> or Group Separator (ASCII 29), as per the GS1 DataMatrix symbology specification. As with GS1-128, the FNC1 character at the beginning of the symbol has another purpose and is never transmitted.

GUIDELINE RECOMMENDATION

The GS1-128 and GS1 DataMatrix symbols should be printed as black bars on a white pressure-sensitive label using, for example, the thermal-transfer printing process. 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 greater precision and better 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; 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 Table 1).

The HRI of the primary GTIN + Serial Number bar code shall be printed directly beneath the bar code. The GTIN Application Identifier in parentheses "(01)," then the Indicator digit ("5" in the examples herein), the two-digit "03" GS1 prefix for an NDC embedded within a GTIN, the NDC itself, the GTIN mod-10 check digit; then the serial number application identifier in parentheses "(21)" followed by the serial number data. Each of these elements shall be separated by a single space. The nominal 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. In the preferred embodiment, this string includes the expiration date AI in parentheses "(17)" followed by 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 in this precise 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 this 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 nominal font size of this human-readable string is 12 points.

A 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 HDA 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 that shown. This may result in the necessity to use a wider label or a smaller X-dimension. Before using a smaller X-dimension, be certain that your GS1-128 symbol is optimized to produce the shortest possible symbol per 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 that shown. This may result in the necessity to use a wider label or smaller X-dimension. Before using a smaller X-dimension, be certain that your GS1-128 symbol is optimized to produce the shortest possible symbol per 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:

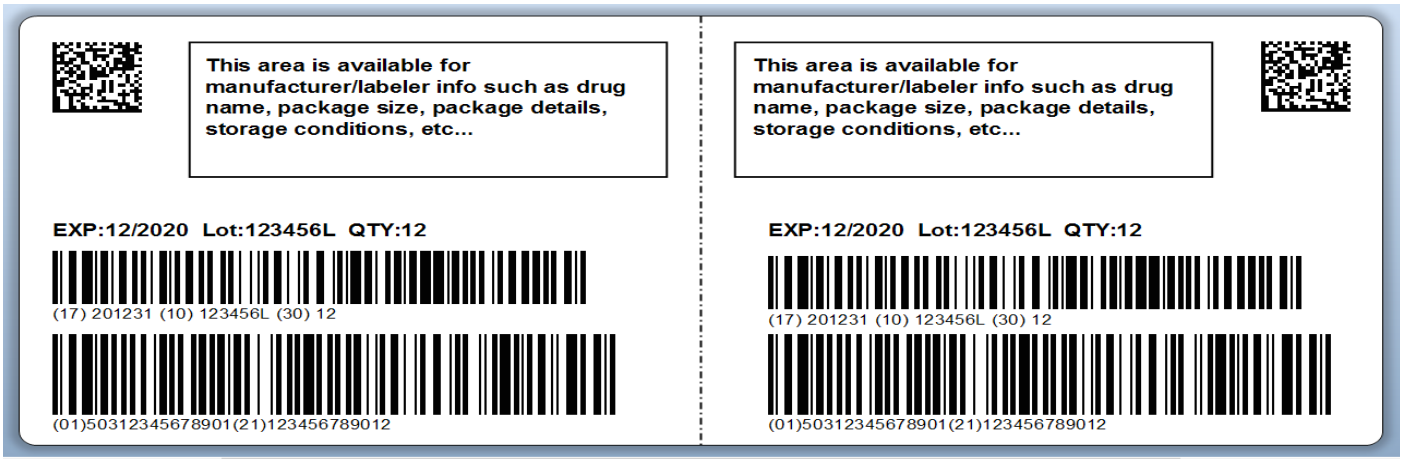
Note: The combined primary and secondary data string encoded in the 2D GS1 DataMatrix symbol must be exactly the same AIs, data elements, with the exception of quantity, and FNC1 separator characters as are encoded in the individual primary and secondary data GS1-128 symbols. See Note 2 in Table 1 for 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

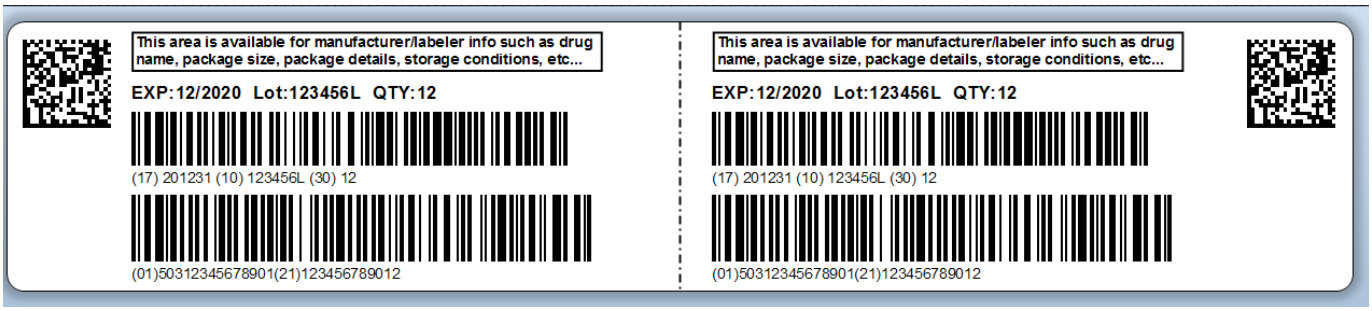
Label size is 4.00"x10.00"; GS1-128 X-dimension is 19.1 mils; GS1 DataMatrix X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.75" tall; secondary EXP + LOT + QTY is 0.50" tall. GS1 DataMatrix is a 22x22 matrix, therefore 0.66"x0.66". HRI is 10-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY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



FORMAT 1, EXAMPLE 2: SMALLEST HEIGHT LABEL

PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, SERIALIZED CORNER WRAP

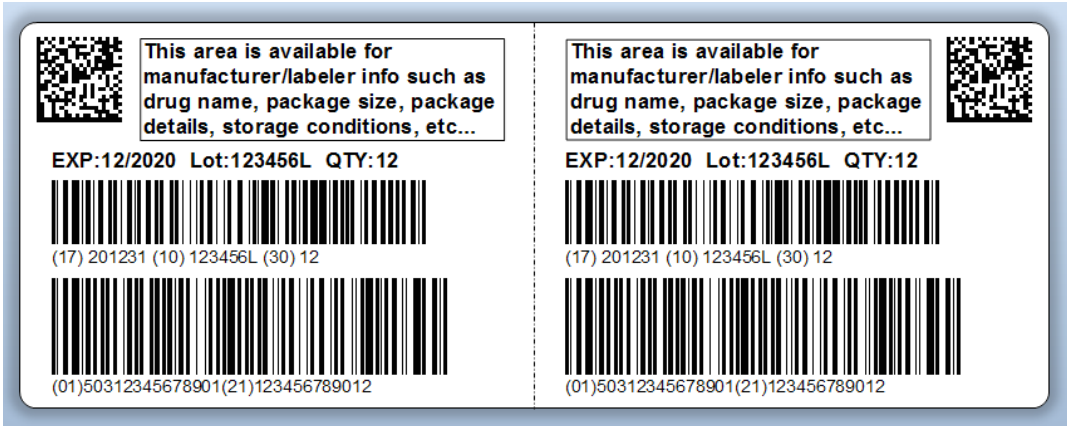
Label size is 2.00”x10.00”; GS1-128 X-dimension is 15.8 mils; GS1 DataMatrix X-dimension is 30.8 mils. Primary GTIN + Serial Number is 0.50” tall; secondary EXP + LOT + QTY is 0.40” tall. GS1 DataMatrix is a 22x22 matrix, therefore 0.66”x 0.66”. HRI is 8-point Arial Bold (Zebra Smooth) for both. EXP/LOT/QTY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



FORMAT 1, EXAMPLE 3: SMALLEST WIDTH LABEL

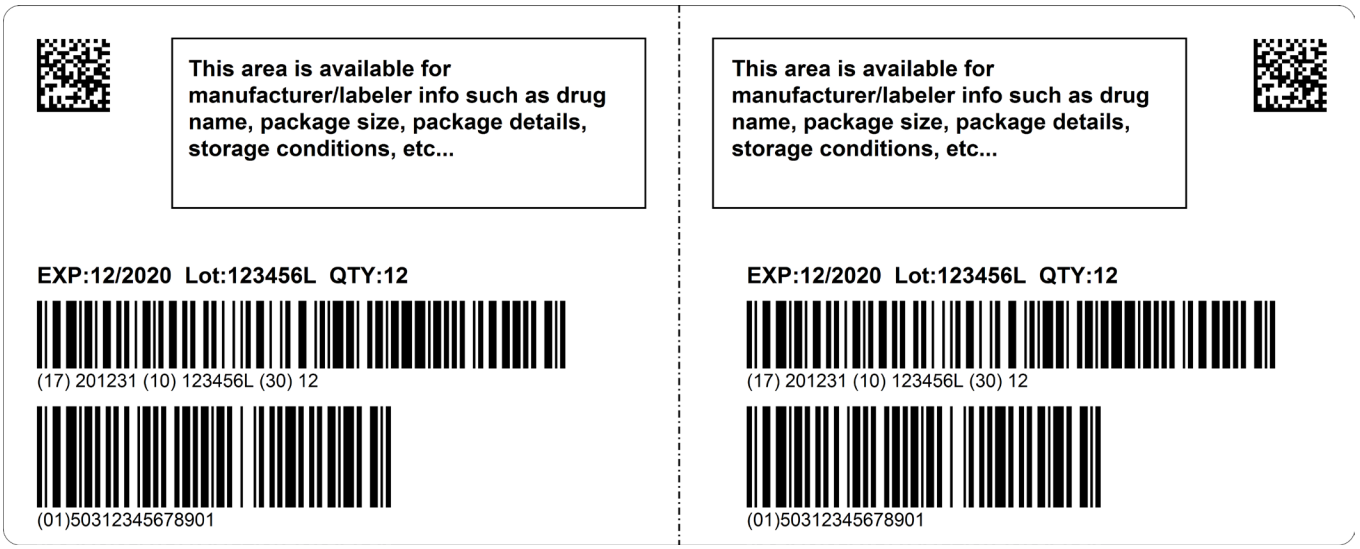
PRODUCT IDENTIFICATION LABEL: HOMOGENEOUS CASE, SERIALIZED CORNER WRAP

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 upon the length of the serial number, and the possible use of alpha characters in the serial number, some flexibility in 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 under these circumstances.*



FORMAT 2 LABEL

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 nevertheless 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.



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 (ASCII 29), 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. They are shown in the preferred order: AI(01) GTIN, AI(17) EXP DATE and AI(10) LOT.

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, be certain that your GS1-128 symbol is optimized to produce the shortest possible symbol per 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:

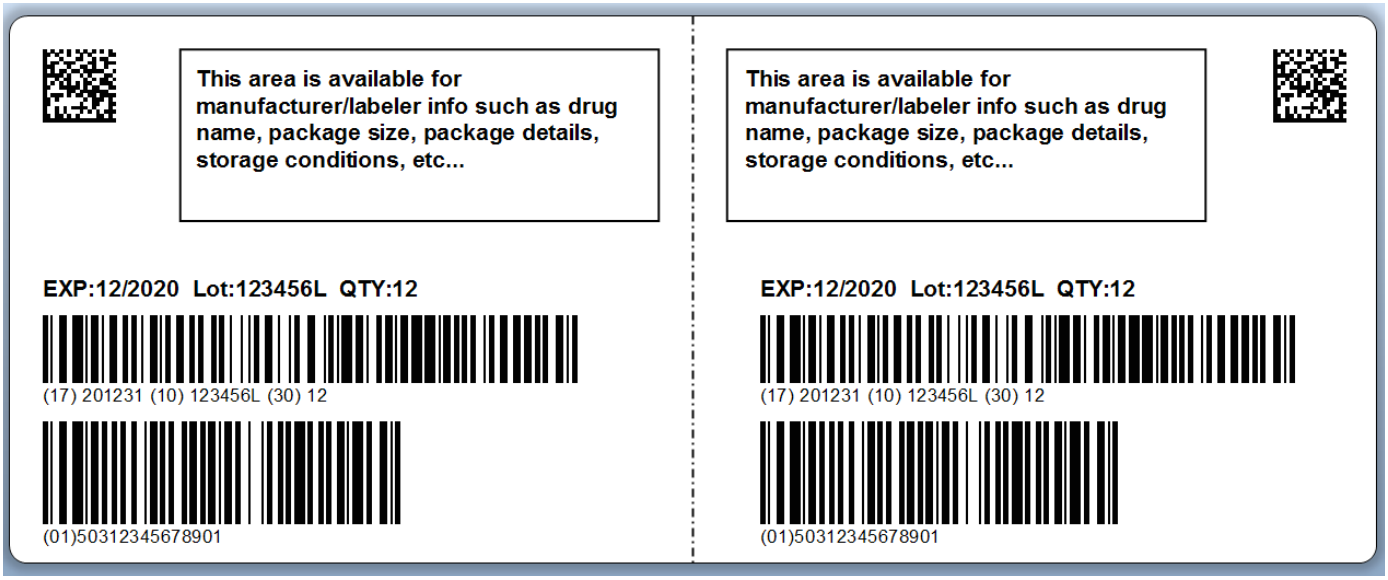
Note: The combined primary and secondary data string encoded in the GS1 DataMatrix symbol should use the same AIs/data elements, except for quantity and FNC1 separator characters, as these are encoded in the individual primary and secondary data GS1-128 symbols. See Note 2 in Table 1 for the precise encoding model.

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

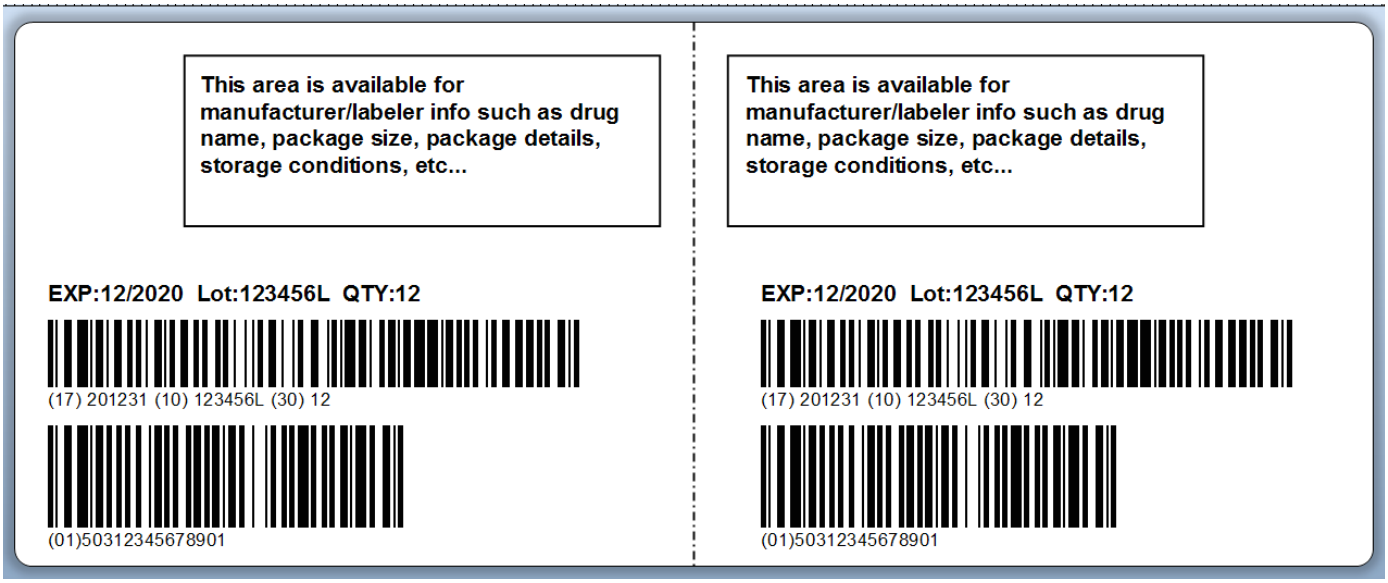
FORMAT 2, EXAMPLE 1: PREFERRED MINIMUM LABEL SIZE

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.



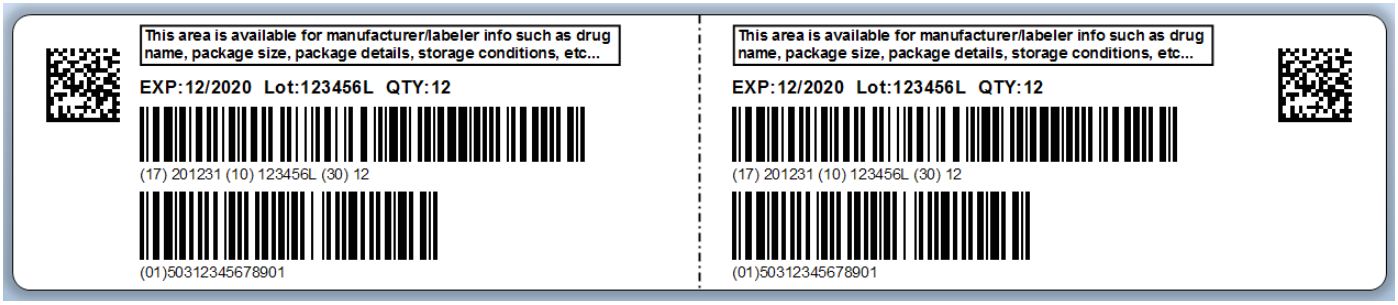
Or:



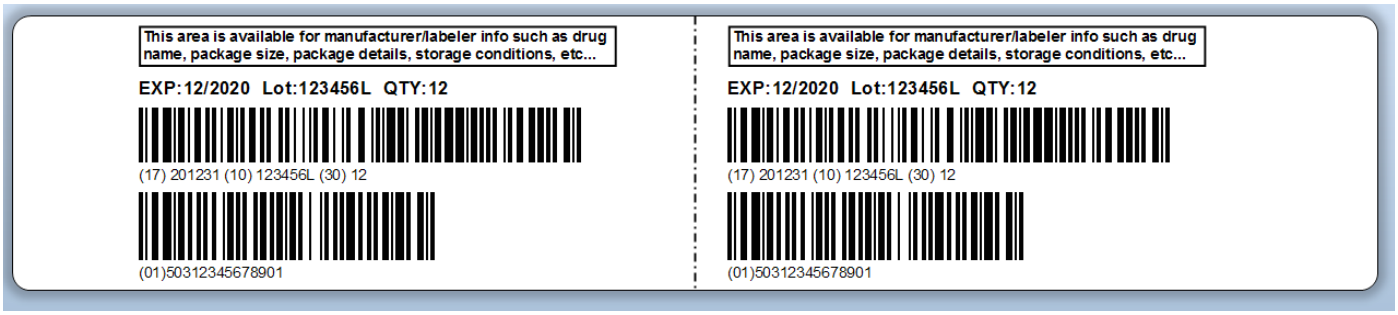
FORMAT 2, EXAMPLE 2: SMALLEST HEIGHT LABEL

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.



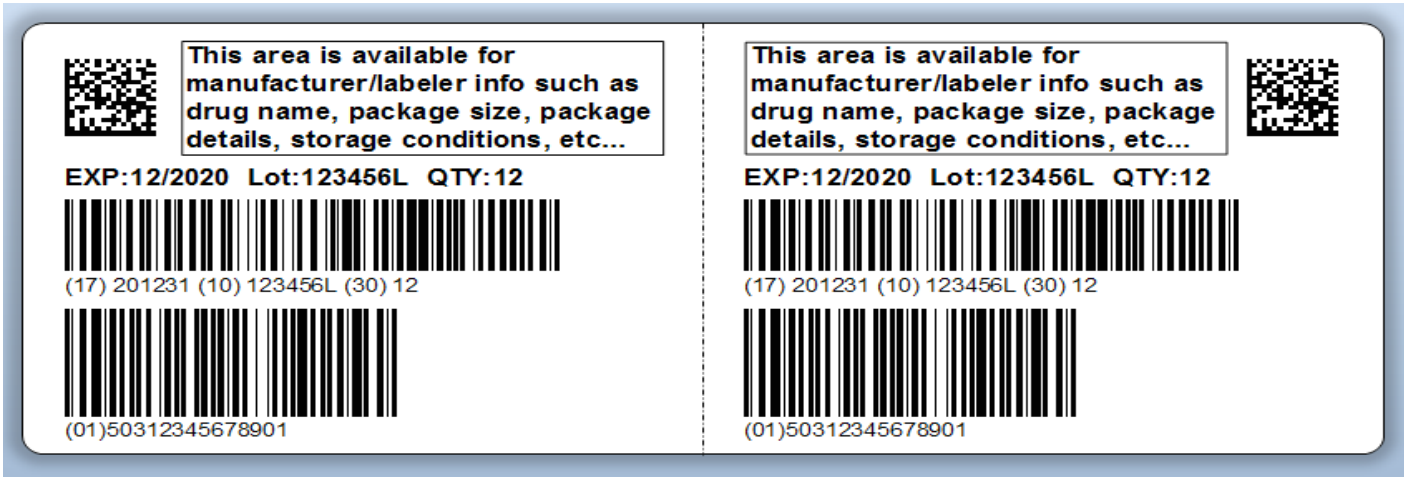
Or:



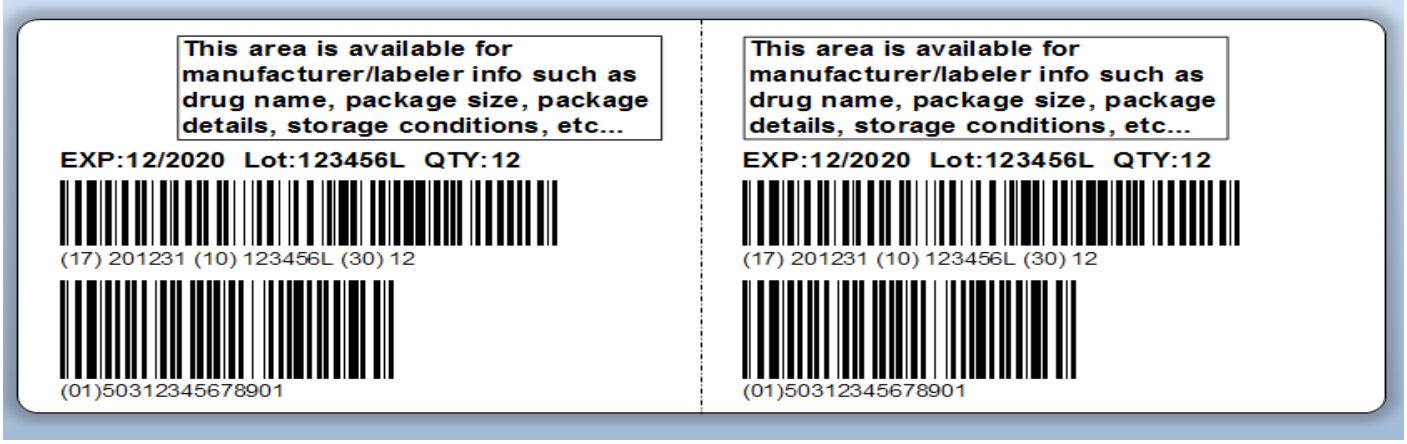
FORMAT 2, EXAMPLE 3: SMALLEST WIDTH LABEL

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.



Or:



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 with this standard with respect 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.

Case Marking and Labeling

GUIDELINE RECOMMENDATION

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. Other printing methods are acceptable, for example, laser ablation on a black or other dark 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.

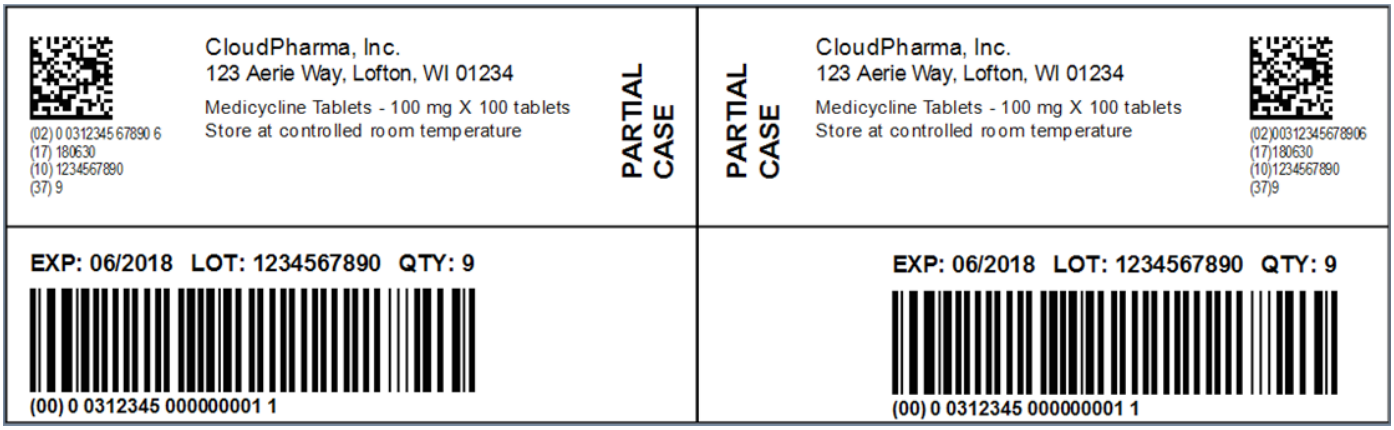
Partial Homogeneous Case and Non-Homogeneous Case

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 use of AI(02) and AI(37) is not recommended by GS1 US and is not intended for labeling of trade items. Although not pictured below, 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.



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[59]

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. See the following example:

59 It is the position of these guidelines that 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.

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.

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[60] set out the SSCC label format. The relevant sections [section 2.2 *Logistics Units* and section 3.3.1 *Identification of a Logistics Unit AI(00)*] of the GS1 General Specifications 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.

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

The label itself will 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 in substance 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)

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 certain 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 for additional details.

The following diagram is an example of the 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"

- **Carrier Identification:** This field's 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 to 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 Fig. A).

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 Fig. B).

Multiple Data Carriers on Logistical Containers

If a trading partner applies two different labels for the same purpose (e.g., an SSCC bar code label and an SSCC encoded in an RFID tag), the serial numbers must be the same. The same would hold true for product identification information encoded in a bar code label and an RFID tag. A single container may contain a product ID label and an SSCC label with two different serial numbers. These labels are intended for different purposes so two different serial numbers would be acceptable. 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 (Fig. C), 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.

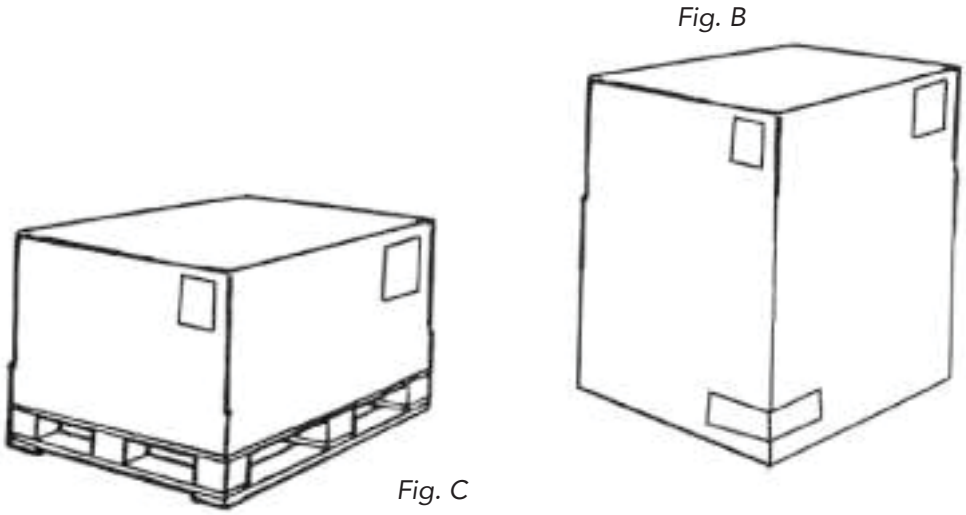


Fig. B

Fig. C

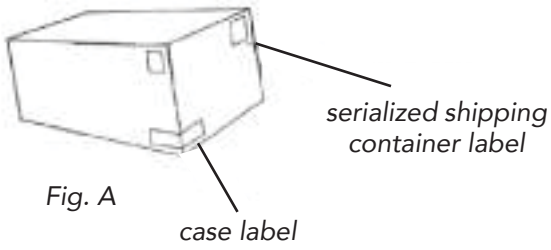


Fig. A

GUIDELINE RECOMMENDATION

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

Also recommended is bar coding the narrow side (or front) of the case (one side minimum) for single case 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 correct only with respect to the UPC symbology (and, in the past, ITF-14, the use of which is no longer endorsed by the 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 currently 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.[61] The NDC drug listing requirements apply to all drugs.[62]

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 UPC 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 UPC 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.

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.

61 § 581(11),(12), 21 U.S.C. § 360eee(11),(12).

62 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. 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.

TECHNOLOGY CONSIDERATIONS

Bar Code Scanners

As the industry moves toward DSCSA implementation, the use of GS1 DataMatrix 2D symbology is increasing rapidly throughout the global pharmaceutical supply chain as means of compliance with the DSCSA and other requirements. 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. And, 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 label on the shipping container, to the receiving dock, the hospital supply room, patient bedside and beyond, 2D bar codes are becoming increasingly prevalent and eventually will be necessary 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-id 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 has to 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 (as most certainly do).

Knowing which symbology has been scanned is a critical piece of information to have in most any application but most necessary 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 correct branch in their logic for the next step in data processing. Knowing, for example, that one has scanned a UPC or GS1 DataBar or GS1-128 symbol determines that the proper logic branch is the one that handles 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.)

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 one knows by the ISO/IEC Symbology Identifier that one has 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 the proper logic branch is the one that handles 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 must be taken into consideration when designing and implementing any bar code scanning solution. 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 are just a few important considerations. 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. And 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 certainly 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 DataMatrix 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, not only for use at the point of care, 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, battery life and more.

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 no longer recommend GS1 DataBar as alternative data carriers due to negative feedback regarding the ability for some older scanning systems to read these bar codes. UPC-A is preferred. 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.
- 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.
- 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, labelling 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). However, for those sold to a trading partner, including the word "partial" and a SSCC is recommended.
- Non-homogeneous or mixed-product cases should include a SSCC.

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