



FDA Meets Deadline for DEVELOPMENT OF THE STANDARDIZED NUMERICAL IDENTIFIER (SNI)

AT THE END OF MARCH, just shy of the statutory deadline, the U.S. Food and Drug Administration (FDA) issued final guidance, “Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages” (Final Guidance). The Final Guidance identifies the standardized numerical identifier (SNI) that should be used for package level identification in the U.S. The Final Guidance defines package level as the smallest unit of sale that is placed in interstate commerce by the manufacturer or repackager that will be dispensed by the pharmacy.¹ The Final Guidance states that the SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). At this time, the sNDC is not a federal requirement. The Final Guidance only delineates the standard that FDA has developed which may be part of future legislation and subsequent FDA regulations.

What is the sNDC?

The sNDC is a combination of the National Drug Code (NDC)² and a unique serial number. The sNDC is generated by the manufacturer or repackager, for each individual package and should have no more than 20 characters (letters and/or numbers). The Final Guidance emphasized that the scope of the document is limited—it does not cover implementation nor does it address other standards for validation, authentication, and tracking and tracing of prescription drugs. The FDA stated this is an initial step and will be the first of a series of guidance documents related to Section 505D of the Federal Food and Drug and Cosmetic Act (the Act).

Why is Section 505D important for the FDA?

Section 505D was created through the enactment of the Food and Drug Administration Amendments Act of 2007 (FDAAA). It requires the FDA to “develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.”³ Specifically, Section 505D created a hard deadline for the FDA to meet regarding development of a SNI. FDA was required within 30 months of enactment of FDAAA to develop a SNI that would be applied to a prescription drug at the point of manufacturing and repackaging, at the package or pallet level, and be

sufficient enough to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.⁴ Section 505D also required FDA to consult with a wide range of groups during the development process and harmonize with international standards.

FDA began the public consultation process for the development of the SNI in 2008. FDA issued a Federal Register (FR) Notice seeking information from drug manufacturers, distributors, pharmacies, and other interested parties.⁵ The FR Notice asked a series of questions soliciting specifics like: whether the SNI should contain recognizable characteristics or be random codes; should the SNI include the lot number; or should the SNI be machine readable or human readable. The FR Notice also delineated a series of questions on standards for validation, track and trace, and authentication and asked for input on how the FDA should prioritize the development and identification of these standards. According to the FDA, the input received from this FR Notice was used to create the “Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages” (Draft Guidance) that was issued in January of 2009.⁶ In general, there were no unforeseen changes made to the Final Guidance.

The Final Guidance is compatible with an internationally recognized standard – GTIN, which was established by GS1. The GTIN is a global standard for item and object identification. The GTIN can be serialized using an Application Identifier (A1)

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to create a serialized GTIN (sGTIN)¹. As other countries consider legislation or regulatory requirements related to serialization, continued support and use of this global standard will be imperative for the global pharmaceutical supply chain. PPTA was active throughout this guidance development process and was pleased to see that comments made to the

Draft Guidance by the association and others from industry materialized to changes published in the Final Guidance. PPTA commends the FDA on the process for developing this guidance, in particular the ability of the Agency to issue final guidance within a reasonable amount of time. It is safe to say that a looming statutory deadline always helps and goes to show everyone needs a deadline.

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¹ Guidance for Industry: Standards for Securing the Drug Supply Chain – Standardized Identification for Prescription Drug Packages

² 21 CFR Part 207 defines the NDC, which corresponds to the specific drug product

³ FDA ACT § 505(D)(a)

⁴ FDA ACT § 505(D)(b)

⁵ Federal Register: Vol. 73. No.55, March 20, 2008

⁶ Federal Register: Vol. 74. No. 11, January 16, 2009

EXAMPLE OF A SERIALIZED NATIONAL DRUG CODE (sNDC)

NDC

55555 666 77

+

SERIAL NUMBER

11111111111111111111

labeler code + product code + package code

unique, up to 20 characters