

Example of a Serialized National Drug Code (sNDC)		
NDC		SERIAL NUMBER
55555 666 77	+	11111111111111111111
Labeler code + product code unique, up to 20 characters + package code		

FIGURE 4.3

An sNDC example. (From *Guidance for Industry: Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages*, U.S. Food and Drug Administration, 2010, p. 7, <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf>.)

authentication always surfaces. However, in many to most cases, the definition of *authentication* is skewed toward authentication of the packaging. The logic seems to be, if you can authenticate the packaging, you can authenticate the pharmaceutical drugs in the packaging.

In March 2010, the FDA issued its *Guidance for Industry Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages*.²⁴ This guidance calls for the development of a standard numerical identification (SNI) to be applied to the smallest package for individual sale in a pharmacy. The basis for the SNI is a serialized National Drug Code (sNDC) (see Figure 4.3).

As we mentioned at the start of this chapter, the supply chain participants are now being asked to establish the processes and systems to verify the product identifier (or SNI). Of course, this is a good start to secure the pharmaceutical drug supply chain. However, verifying the product identifier only verifies the “license plate.” In my opinion, this is *not* product authentication. I have always defined *product authentication* as confirming truth or integrity of the pharmaceutical drug. When all is said and done, the people responsible for patient safety and the patients want the drug product authenticated. Verifying the product identifier is only one step to product authentication.

ENTER THE BAD GUYS—AND GALS

The FDA asking the supply chain participants to establish the process and systems to verify the product identifier potentially leaves the door wide open for the bad guys and gals to figure out how to beat the system. If the process and systems that are developed get too granular, they are at risk for substitution and circumvention.