



April 10, 2009

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2009-D-0001, Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages (draft guidance). As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP can offer unique and vital feedback on this important health care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely, effectively, and in a cost-conscious manner.

ASHP understands that FDA has been directed by statute to develop a standardized numerical identifier (SNI) to be applied to a prescription drug at the point of manufacturing and repackaging at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. Further, the draft guidance only addresses package-level SNI.

FDA has determined that the SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) that reflects each corresponding manufacturer or repackager, combined with a unique 8-digit numerical serial number generated by the manufacturer or repackager for each individual package.

ASHP understands the need for the sNDC, however, the Society is concerned that the NDC does not facilitate the adoption of bar-code-enabled medication administration in hospitals, nor does it address the need to have readable bar codes on every product at the point of care. ASHP encourages FDA to address these issues, and explore the potential

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benefits of supplementing or modifying the NDC with a coding system that can be effectively used across the medication-use continuum.

In the meantime, to ensure consistency and usability of the NDC, ASHP urges FDA to require pharmaceutical manufacturers to use symbologies that are readily deciphered by commonly used scanning equipment to code for the NDC, lot number, and expiration date on all unit-dose, unit-of-use, and injectable drug packaging. ASHP recommends that FDA draft a regulation requiring the assignment of the NDC to drug products in a single, standardized format.

As FDA finalizes the draft guidance, ASHP recommends that the SNI allow for alpha-numeric serial numbers in order to increase the choices for the numbers. As the draft guidance currently stands, the sNDC is an 8-digit numerical serial number. However, it is likely that the permutations for serial numbers will be exhausted in the foreseeable future. For example, assuming that serial numbers are uniquely assigned for each drug code, if a manufacturer produces 20,000,000 units per year of a single-dose injection, the manufacturer will start repeating serial numbers within 5 years, or will have to assign a new NDC to that product. If FDA allows for alpha-numeric serial numbers, it is far less likely that the sNDC will need to be repeated.

ASHP also has concerns that, under the draft guidance, a counterfeiter only needs to know which serial numbers have been issued in order to produce a counterfeit that will be indistinguishable from the genuine article. If the serial number must be unique across all items produced by a given manufacturer or repackager (in which case the counterfeiter must know both the range of the serial numbers and the assignment of those serial numbers to specific products), then the realm of serial numbers gets even smaller, and fails even sooner to provide unique identification. The Society acknowledges that radio-frequency identification is evolving, and the sNDC may be the foundation for interoperability of technologies to maintain the integrity of the medication supply chain.

The Society appreciates this opportunity to present its written comments on the draft guidance. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at [jcoffey@ashp.org](mailto:jcoffey@ashp.org).

Sincerely,



Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs