



March 9, 2009

Division of Dockets Management (FDA-2009-D-0001)
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Re: Docket No. FDA-2009-D-0001: Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages; Availability; Request for Comments

Dear Food and Drug Administration:

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the request for comments on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages.

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,500 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

The standards required for prescription drug identification and track and trace are not within the development expertise of NCPDP, but the use and the securing of the prescription drug supply chain are of acute interest to NCPDP and its members. Within the past year NCPDP has formed a work group to explore the many facets of drug identification, pedigree and track and trace regulations and technologies with a goal of informing the pharmaceutical industry, recommending processes for best practice and facilitating the industry's move to the new standards and technologies.

I. Background

II. Request for Information

A. Serialized National Drug Code (sNDC) described in the draft guidance is appropriate for package level identification for most prescription drugs; however it might not be useful at the pallet or other intermediate level, such as case.

1. Characteristics

- a. Please comment on whether there are any standards that would be appropriate for serialization or other numerical identification at the case or pallet level?*

NCPDP Response:

If traceability is to become a reality, the parties in the supply chain need to ensure that the numbers are unique to individual physical objects. The criteria and processes for initiating and authenticating the identifier must be agreed to and implemented prior to the implementation of the identifier in the supply chain. The identifiers used must be able to support uniqueness not only at the unit or product level, but also at the package, case, pallet, tote, and shipping container levels.

The numerical identifier should be both human and machine readable to support independent pharmacies that may not have elaborate pharmacy management systems to track their supplies. In addition, states such as California and Florida have already approved pedigree standards to support both paper and electronic product validation and tracking.

B. FDA's draft guidance recommends Standardized Numerical Identifier (SNI) for most prescriptions drug packages be an sNDC, consisting of the NDC plus a unique 8-digit numerical serial number

1. Some comments recommend that the SNI allow for alpha-numeric serial numbers in order to increase the choices for the numbers.

- a. Given the FDA recommendation for SNI, please comment on the necessity of having the serial number allow for alpha-numeric possibilities and under what standards this might be achieved?*

NCPDP Response:

NCPDP would recommend that the serial number be increased to nine digits in order to support high volume pharmaceutical products. It is important that a number not be recycled while a particular serialized product remains in the supply chain.

C. Blood and blood components

1. Blood and blood components currently use either the ISBT 128 standard or Codabar for product package identification. In addition, hematopoietic stem cells derived from peripheral and cord blood use the ISBT 128 standard for product identification.

- a. Please comment on whether these standards should be designated as the SNI for such products?*

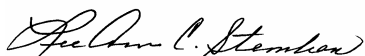
NCPDP Response:

NCPDP supports the use of the ISBT 128 for standardized identification and information transfer of key information regarding blood, blood derivatives, tissues and organs. This global standard provides the information necessary for traceability and secure supply of these products in the current supply chain environment using bar code, data matrix and RFID technologies. This global standard provides specifications for machine and human readable information and package labeling. This complex multi level data structure is not compatible with the proposed SNI as it is alpha-numeric, has multiple parts and is not 18 digits in length.

Conclusion

NCPDP stands ready to assist the FDA in providing education for the pharmaceutical industry and achieving consensus and support for the implementation of standards to secure the drug supply chain. Thank you for the opportunity to respond to this request for comments.

Sincerely,



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President

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cc: NCPDP Board of Trustees