

05n-0403-ereg011.txt

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Public Comments on Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Bi ologi cs License Application, and Animal Drugs; Public Meeting; Extension of Comment Period: =====

Title: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Bi ologi cs License Application, and Animal Drugs; Public Meeting; Extension of Comment Period  
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General Comment:GS1 US comments to Federal register; August 29,2006 (volume 71,number 167))  
( PROPOSED RULES) (PAGE 51275-51357) (DOCKET NO. 2005N-04030)RIN 0910-AA490

The global GS1 system can not accommodate the inclusion of an 11 digit NDC or an alpha numeric NDC in the GTIN. Such changes will cause disruption in global commerce as all retail, and grocery data bases worldwide utilize the GS1 system. The hundreds of thousand of scanners and their accompanying data bases would have to be revised drastically. This FDA course could be responded to by other countries allowing their own unique numbering system, further fractionalizing the global system of commerce. The ten digit NDC was encoded in the GS1 Global Trade Item (GTIN) in the 1970s before the GS1 began its global expansion. As such the US NDC GTIN construct is grandfathered into the system. Such a nation centric code would not be included in the GS1 system today, as it would lead to marginalization of the entire system.

2. To resolve this issue and forestall these consequences, GS1 US recommends that the NDC be removed as a primary indicator in automated identification (bar code). The FDA should adopt the commercial GTIN without the NDC encoded as the data structure for all futures bar-coding efforts. Any GTIN with a NDC already encoded and used would be grandfathered but no new ones would be introduced. The FDA should rely on the system that is used and delivers 100% reliability and accuracy in global retail and grocery industrial sectors--- the GS1 system. Once the FDA removed the NDC as a requirement in bar coding, the NDC could lengthen to satisfy the data capture needs. Another possibility, is that the lengthened NDC could, if a global need arose, become a secondary attribute of an item and receive its own application identifier similar to the NATO Stock Number (NSN)

3. The FDA should allow the use of data matrix as a symbology carrier for all healthcare products.

This 2d symbol had been adopted in the GS1 system since 2004. It is in widespread use in many industries either as a primary or secondary symbol. . The cost of imagers to read it is competitive with laser scanners. The pharmaceutical manufacturers who are currently printing linear codes to satisfy the 2004 FDA requirement would switch to the use of data matrix on many items

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almost immediately. Many US hospital systems such as Brigham and Women's and the USA Veterans Hospital system employ only imagers so its adoption would not cause disruption at the provider.

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