



HUG Letter to US FDA Recommendations

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Recommendations

Recommendation 1

- Permit labelers to barcode GTINs without embedded NDC numbers, as long as they follow GS1 allocations rules and standard structure
- Labelers to maintain and manage relationship between NDCs and associated GTINs

Recommendation 2

- Permit labelers to barcode using DataMatrix 2-D barcode structure



Recommendation 1

Justification

- Reduce country specific identifiers in barcodes to increase efficiency and ability of global labelers to provide multi-national labeled product to global customers
- Reduce mutually exclusive country specific implementations and infrastructure

Impact

- Stock-out reduction in US market
- Cost reduction and increased efficiency in global supply chain
- No change to current management of NDCs
- US FDA afforded flexibility to change NDCs without impacting GTIN structures used in barcodes
- Consumers: minimal impact except possibly update database



Recommendation 2

Justification

- Advantages of DataMatrix over linear barcode symbologies:
 - Smaller; more robust; more data storage
- Additional features:
 - Within ISO&GS1 standards; most technology verifiable 2-D code
 - Utilized on pharmaceutical packaging globally, outside US
 - Preferred code for direct part marking: leverageable to devices

Impact

- Maximum standardization in healthcare and across global regions
- Minimal impact on packaging operations
- Include dynamic information (eg. lot number and expiry date)
- End-user potential upgrade of legacy systems from laser scanning to image verification



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