

Vada Perkins, BSN, MSc, RN  
CAPT, USPHS, Chief, Business Operations Staff  
US Food and Drug Administration

# **OVERVIEW AND GUIDANCE ON VACCINE 2D BARCODING**

"Reviewed April 2013"



# 2D Bar Code Implementation: FDA/CBER Overview for Vaccines

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Vada Perkins, CAPT, USPHS  
Chief, Business Operations Staff  
FDA/CBER/OD



# Background

- *Federal Register* of February 26, 2004 (69 FR 9120)
  - Bar Code Label Requirements for Human Drug Products and Biological Products
- Guidance for Industry: Bar Code Label Requirements Questions and Answers (August 2011)
- [Docket No. FDA–2011–N–0719]-Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563



# *Federal Register* of February 26, 2004 (69 FR 9120)

- Final rule requiring certain human drug and biological products to have on their labels a linear bar code that contains, at a minimum, the drug's NDC number (21 CFR 201.25)

# Bar Code Requirements

## 1 of 2

- Drugs approved on or after April 26, 2004, have 60 days from their approval date to comply with the bar code requirement (21 CFR 201.25)
- All other drugs subject to the bar code requirement, including drugs with applications approved before April 26, 2004, must implement the requirements within 2 years of the effective date (i.e., no later than April 26, 2006) (21 CFR 201.25)



# Bar Code Requirements

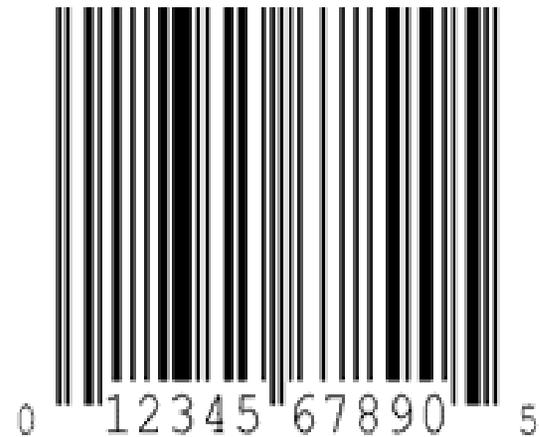
## 2 of 2

- A drug manufactured on or after April 26, 2006, must bear a bar code
  - A drug manufactured and distributed by the manufacturer before April 26, 2006, will not need to be recalled or repacked to bear a bar code.



# Linear Bar Code

- 12 Numeric





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# 2-Dimensional Bar Codes



# Appearance of Human Readable Information



GTIN(01): 03453120000011  
EXPIRY(17): 2012-11-25 (yyyy-mm-dd)  
BATCH/LOT(10): ABCD1234





## Bar Code Q & A: Q12

- FDA will consider requests from vaccine manufacturers who request to use an alternative regulatory program, comprised of alternative technology such as two dimensional symbology, that encodes, for example, **the lot number and expiration date**, because use of this technology may enhance health care providers' ability to keep records and report adverse events as required under the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) (42 U.S.C. 300aa-25(a)).
- FDA recognizes that it may be infeasible for a vaccine manufacturer to implement alternate coding technology for childhood vaccines only, while retaining linear bar coding for its other vaccines due to practical considerations related to manufacturing and cost. We will therefore consider a manufacturer's request for such an exemption for other licensed vaccines in addition to childhood vaccines."



# 2D Bar Code: CBER Product Office Review



## 2D Bar Code Product Data Elements: CBER Product Office Review

- 2D bar code to include the following:
  - National Drug Code (can support GTIN)
  - Lot Number
  - Expiration Date
- \*Supports Serialized NDC (sNDC)
  - *Guidance for Industry: Standards for Securing the Drug-Standardized Numerical Identification for Prescription Drug Packages (Final Guidance)- March 2010*
  - Unique alphanumeric identifier (up to 20 characters)
    - NDC + Serial Number
      - » **12345-67-890 +1m35rtf67h**

## FDA/CBER Labeling Submission: Addition of a 2D Bar Code

- Industry request: In addition to the current bar code requirements (linear), allow for a 2D Bar Code to be included on existing product labels
- **Prior Approval Supplement (PAS)** Labeling Submission
  - Requires review of label and contents
    - Reformatting/placement of label information
  - May consider a **CBE (Changes Being Effected)** supplement in the future
    - Gather more experience (FDA and Industry)
    - Regulatory approach for CBE vs. PAS submission

## FDA/CBER Review Process: Addition of a 2D Bar Code

- Review of data elements to be included within the 2D bar code: (*Human readable data elements*)
  - (NDC, Lot #, Expiration Date)
  - Ensure consistency with NDC assignment at the product and package level (e.g., multilevel packaging).
    - Prescribing Information (“How Supplied” section)
    - HL7 Structured Product Labeling (SPL) product data elements
    - Linear bar code
    - Human readable NDC on the carton/container label(s).

# FDA/CBER Review Process Considerations: Addition of a 2D Bar Code

- 2D barcode size, location, and placement (spacing)
  - Arrangement of the 2D bar code with other content on a label
- Content structure and format
  - Ensure consistency with a standard (e.g., GS1)
    - [Readability](#)



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# Equipment/Software/Manufacturing Changes



## Equipment/Software/Manufacturing Changes

- Use of existing labeling equipment: Equipment already has the capability for 2-D barcode and will require validation for this addition to the label
  - [Annual Report \(21 CFR 601.12\(d\)\)](#)
- Applicant needs to add a new labeler
  - [Annual Report \(21 CFR 601.12\(d\)\)](#)

## Equipment/Software/Manufacturing Changes

- New location (under the existing license) for labeling and packaging
  - **CBE-30** in most cases
  - May require an inspection at some point or follow up by Team Biologics
- A new building on the same site will still be under the same quality systems and therefore reviewing as a supplement may not be required.



# Equipment/Software/Manufacturing Changes: CBER Point of Contact

For more information regarding manufacturing changes related to 2D barcode labeling implementation contact:

**Manufacturers Assistance:**

[Industry.Biologics@fda.hhs.gov](mailto:Industry.Biologics@fda.hhs.gov)

Attn: CBER's Division of Manufacturing and Product Quality in the [Office of Compliance and Biologics Quality \(OCBQ\)](#)



# FDA/CBER Review Process: Exemptions



# Barcode Exemption Request: Bar Code Label Requirements (21 CFR 201.25(d))

- **CBER:**
  - Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852
- **CDER:**
  - Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002

# CBER Policy/Procedure: Standard Operating Policies and Procedures (SOPP)

- Revision to external Labeling SOPP
  - Formalize process for external stakeholders
    - [March 2012](#) (approx.)
- Internal CBER business processes developed within the product offices for review of 2D barcode submissions



## [Docket No. FDA–2011–N–0719] Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563

- *“FDA conducting a review of its existing regulations to determine whether they can be made more effective in light of current public health needs and to take advantage of and support advances in innovation”*
  - Initial comments: [9 January, 2012](#)
  - Reply comments: [23 February, 2012](#)
- Link to Docket:  
<http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR%252BPS;rpp=10;po=0;D=FDA-2011-N-0719>



# FDA Questions for the Breakout Session

1) *What is the structure and format to be incorporated in the 2D barcode (e.g., GS1 standard)?*

2) *Will 2D barcodes be placed on both the carton and container label(s)?*

3) *What are the business processes for scanning and recording product to be administered ?*

*For example:*

a) *A vaccine supplied as a kit and requires reconstitution*

*-active component to active component*

*-active component to diluent*

b) *Pre-filled syringe*

4) *What is the data source (drug repository) for the system or systems (if a data source exists)?*

5) *Have manufacturers confirmed that they are currently in compliance with the bar code rule?*



# Thank You

## Contact Information

[vada.perkins@fda.hhs.gov](mailto:vada.perkins@fda.hhs.gov)

**QUESTIONS?**