APPENDIX A: Bar Codes

Introduction

FDA regulations require that certain human drug and biological product labels contain a linear bar code consisting of, at a minimum, the National Drug Code (NDC) number (21 CFR 201.25).

The information presented in this Appendix is specific to the addition of a 2D Bar Code in relation to question 12 of the "Guidance for Industry: Bar Code Label Requirements—Questions and Answers" dated August 2011.

For linear bar code requirements, please refer to Final Rule: Federal Register of February 26, 2004 (69 FR 9120) Bar Code Label Requirements for Human Drug Products and Biological Products.

Exemption requests from the linear bar code rule should be submitted, per 21 CFR 201.25 (d)(1)(ii), to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center,10903 New Hampshire Ave, Bldg. 71, Rm G112, Silver Spring, MD 20903-0002.

Procedures for the Addition of a 2D Barcode

I. Labeling Submissions:

A. Submissions for 2D bar code labeling should be submitted to CBER as a Prior Approval Supplement (PAS).

B. If you have implemented 2D bar code technology to your carton/container labels without notification to CBER, you should contact the appropriate product office to determine the best mechanism for reporting.

C. The labeling submission should contain the following information:

1. Content of Labeling (SPL).

2. A representative sample of the carton/container label for each presentation of the packaged product.

3. The 2D bar code should contain the NDC, lot number and expiration date of the product.

4. The structure of the data within the 2D bar code should be consistent with an appropriate standard (e.g., GS1).

   a. The information contained within the 2D bar code should be submitted in human readable format to facilitate review.

II. In addition to the labeling review outlined in the SOPP, as applicable to the submission, labeling review for 2D bar code submissions will consist of the following:

A. Structure, content and format of the data elements (e.g., NDC, lot number, expiration date) contained within the 2D bar code.

B. Size and placement of the 2D bar code on the representative carton/container label(s).

C. Manufacturing Changes:

1. Changes to manufacturing equipment or software in support of 2D bar code labeling will likely not require submission of a supplement and be submitted in and annual report under 21 CFR 601.12(d).

2. Please contact CBER's Office of Compliance and Biologics Quality (OCBQ), Division of Manufacturing and Product Quality (DMPQ), for more information regarding manufacturing changes related to 2D bar code implementation.