Guidance for Industry

Bar Code Label Requirements—Questions and Answers (Question 12 Update)

DRAFT GUIDANCE

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Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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For questions on the content of this guidance, contact OCOD at the phone numbers listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
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Contains Nonbinding Recommendations

Draft – Not for Implementation

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I. INTRODUCTION

FDA regulations require that certain human drug and biological product labels contain a bar code (21 CFR 201.25). This guidance provides you, manufacturers of a licensed vaccine, with advice concerning compliance with the bar code label requirements. Previously, FDA issued questions and answers regarding how the bar code label requirements apply to specific products or circumstances in the final guidance entitled "Bar Code Label Requirements—Questions and Answers," dated October 2006 (Oct. 5, 2006, 71 FR 58739) (Bar Code Guidance). These questions and answers can be found at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073354.htm. In this guidance, FDA is proposing to amend our response to question 12 (Q12) in the Bar Code Guidance to provide recommendations to manufacturers of licensed vaccines in connection with the use of alternative coding technologies. We are revising our response because we believe that an alternative regulatory program, comprised of alternative technology such as two dimensional symbology could render the use of linear bar codes unnecessary for patient safety and could enhance health care providers' ability to comply with the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) (42 U.S.C. 300aa-25(a))) (NCVIA). We would consider granting a request for exemption to the bar code requirement pursuant to 21 CFR 201.25(d)(1)(ii) in connection with such use. When this guidance is finalized, we intend to incorporate the revised response to Q12 into the Bar Code Guidance, but otherwise continue with our recommendations for bar code label requirements as currently provided in the Bar Code Guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

In the Federal Register of March 14, 2003, we announced the proposal of new § 201.25 entitled "Bar Code Label Requirements" (68 FR 12500). In the Federal Register of February 26, 2004, the rule was finalized (69 FR 9120). In both the proposed preamble to § 201.25 (68 FR 12500 at 12505) and in the preamble to the final rule (69 FR 9120 at 9126), FDA noted that we were sensitive to possible adverse impacts on vaccine production and availability resulting from making vaccines subject to the bar code label requirements. While vaccines are subject to the final rule's bar code requirements by virtue of being prescription drugs (21 CFR 201.25(b)(1)), we declined to require the inclusion of lot number and expiration date information in a vaccine's bar code information because we determined that the costs associated with encoding lot number and expiration date information appeared to exceed the benefits (69 FR 9120 at 9127). Nevertheless we stated in the preamble to the final rule that we did not intend to object if a vaccine manufacturer voluntarily encodes lot number and expiration date information in its bar code. Id.

Since we issued the bar code final rule, it has become increasingly clear that vaccines present unique concerns in the bar coding context, particularly with respect to compliance with record keeping and mandatory adverse event reporting requirements that are specific to the administration of childhood vaccines. [1] These concerns are particularly important, because vaccines are typically administered in an office or clinic which may have limited administrative support. For example, health care providers who administer a vaccine that is subject to the requirements in NCVIA are required to ensure that there is recorded in the vaccine recipient's permanent medical record (or in a permanent office log or file) the date the vaccine was administered, the manufacturer, lot number of the vaccine, and the name, address, and title of the person administering the vaccine (42 USC 300aa-25(a)). Manual data entry of this information requires rigorous procedures to ensure accurate records as not all this information is encoded. Such manual entry of data may decrease medical practice efficiency as well as increase practice costs, may affect patient safety, and may potentially expose patients to unnecessary or duplicative vaccinations in the event that this information is incorrectly recorded. In addition, clerical recording errors can diminish the value of information available for mandatory adverse event reporting. Furthermore, inaccurate recording of a lot number may delay or misdirect FDA's investigation of an adverse event. In the preamble to proposed § 201.25, we noted that a bar code on vaccines could help ensure the accuracy of certain of these records, but that other technologies may be able to encode more data than linear bar codes (68 FR 12505 and 12509).

At this time, FDA believes that two dimensional symbology technology has advanced such that health care providers may wish to invest in the technology to capture information from a 2-dimensional code because, through use of this technology, they may more effectively be able to address the reporting requirements reflected in NCVIA. This in turn would support compliance

[1] The NCVIA requires health care providers to report certain adverse events related to identified childhood vaccines to the Vaccine Adverse Event Reporting System (42 USC 300aa-25(b)). Although health care providers are encouraged to report adverse events related to other drugs and biological products to FDA, they are not required to do so.

with NCVIA, which established the National Vaccine Program Office (NVPO) in the Department of Health and Human Services (DHHS) to coordinate immunization-related activities between all DHHS agencies including the Centers for Disease Control and Prevention (CDC), FDA, National Institutes of Health (NIH), and the Health Resources and Services Administration (HRSA). The ready availability of information in machine readable format also will enable compliance with the mandatory reporting of adverse events by health care providers under the Vaccine Adverse Event Reporting System (VAERS) administered jointly by CDC and FDA. For example, complete automatic entry of vaccine information would facilitate accurate reporting to VAERS, decrease incorrect VAERS entries, and would facilitate rapid, accurate entry into immunization registries. Finally, the ready availability of information in machine readable format will enable more efficient electronic recordation of information, including lot number and vaccine expiration dates.

For these reasons, FDA now will consider requests from vaccine manufacturers who request to use alternate coding technologies, such as two dimensional symbology, that encode lot number and expiration date information, for an exemption pursuant to 21 CFR 201.25(d)(1)(ii) to the linear bar code requirement. In particular, we will consider granting such an exemption request under 21 CFR 201.25(d)(1)(ii) on the grounds that an alternative regulatory program, comprised of alternative technology such as two dimensional symbology used to facilitate compliance with requirements of public health programs applicable to childhood vaccines, could render the use of linear bar codes unnecessary for patient safety, and we would consider granting a request for an exemption to the bar code requirement pursuant to 21 CFR 201.25(d)(1)(ii) in connection with such use. FDA recognizes that it may be infeasible for a vaccine manufacturer to implement alternate coding technology only for childhood vaccines that are subject to the NCVIA, while retaining linear bar coding for its other vaccines due to practical considerations related to manufacturing and cost. Moreover, the schedule of vaccines subject to the NCVIA is not static and is updated regularly. We therefore will consider a vaccine manufacturer's request for an exemption to the linear bar code requirement for any of its other licensed vaccines in addition to childhood vaccines.

Note that, as we stated in the preamble to the final rule, we continue to emphasize that the general exemption provision in 21 CFR 201.25(d)(1)(ii) is intended to be used in rare cases (69 FR 9120 at 9131). We believe that our proposed revised response to Q12 is consistent with that view because it is narrowly tailored to support the work of the NVPO and to support the quality of adverse event reports that health care providers are required to make to the Vaccine Adverse Event Reporting System, and is responsive to the unique challenges faced by health care providers who administer childhood vaccines in accordance with the NCVIA.

III. RECOMMENDATION

FDA is proposing to revise our response to Q12:

Q12: Can a firm use another automatic identification technology, such as a radio frequency identification chip or a two-dimensional symbology, instead of a linear bar code?

A12: As a general matter, no. The final rule requires the use of a linear bar code to encode the NDC number on most prescription drug products and certain OTC drug products. However, we do not intend to object if firms voluntarily encode lot number and expiration date information, and we recognize that some firms might use other technologies to encode that additional information (response to comment 35, 69 FR 9120 at 9134-9135).

In addition, 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)). In particular, we will consider such an exemption request under 21 CFR 201.25(d)(1)(ii) on the grounds that given the unique concerns regarding vaccines, an alternative regulatory program using alternative coding technology renders the use of a linear bar code unnecessary for patient safety. 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.

Furthermore, as we stated in the preamble to the final rule, we will consider revising the rule to accommodate new technologies (69 FR 9120 at 9138).