

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0426]

Guidance for Industry: Bar Code Label Requirements—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers” dated August 2011. The guidance announced in this notice amends the October 2006 guidance document of the same title by incorporating a revised response to question 12 (Q12). The revised response concerns the ability of vaccine manufacturers to use alternative coding technologies to the linear bar code requirement. The guidance announced in this notice finalizes the draft guidance entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)” dated August 2010, and is superseding the guidance entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers” dated October 2006.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBEB at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM-17), Food and Drug

Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers” dated August 2011. In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA published a final rule (the February 2004 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 national drug code number (§ 201.25 (21 CFR 201.25)). To explain how the bar code label requirements apply to specific products or circumstances, in the **Federal Register** of April 27, 2006 (71 FR 24856), FDA announced the availability of a guidance document entitled “Guidance for Industry: Bar Code Label Requirement—Questions and Answers” that was revised several months later, as discussed in the **Federal Register** of October 5, 2006 (71 FR 58739). Since then, FDA has received additional information concerning vaccines and the linear bar code requirement. In light of this information, we are incorporating a new response to question 12 in the guidance document entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers”. We are providing a revised response to manufacturers of licensed vaccines in connection with the use of alternative coding technologies because it has become increasingly clear that vaccines present unique concerns in the bar coding context, particularly with respect to compliance with recordkeeping and mandatory adverse event reporting requirements that are specific to the administration of childhood vaccines. 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 the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660) (42 U.S.C. 300aa-25(a)) (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 U.S.C. 300aa-25(a)). Manual

data entry of this information requires rigorous procedures to ensure accurate records as not all of this information is encoded and 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. 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 two dimensional code because, through use of this technology, they may more effectively be able to address the reporting requirements reflected in NCVIA.

FDA also believes that enhanced compliance with NCVIA will in turn enable compliance with the mandatory reporting of adverse events by health care providers under the Vaccine Adverse Event Reporting System (VAERS), administered jointly by the Centers for Disease Control and Prevention 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 under § 201.25(d)(1)(ii) to the linear bar code requirement. In particular, the Agency will consider granting such an exemption request under § 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 under § 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 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 NCVIA is not static and is updated regularly. The Agency 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 FDA stated in the preamble to the final rule, the Agency continues to emphasize that the general exemption provision in § 201.25(d)(1)(ii) is intended to be used in rare cases (69 FR 9120 at 9131). FDA believes that its revised response to Q12 is consistent with that view because it is narrowly tailored. Further, as alternative technologies continue to advance, the Agency intends to assess these technologies in relation to current bar coding practices and other FDA initiatives, such as efforts to further enhance the security of the drug supply chain through use of a standardized numerical identifier for uniquely identifying prescription drug packages, and the establishment of a unique device identification system for medical devices.

In the **Federal Register** of September 7, 2010 (75 FR 54347), FDA announced the availability of a draft guidance entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)" dated August 2010. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated August 2010 and incorporates a revised response to question 12 into the guidance entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers". In addition, editorial changes were made to the guidance to improve clarity.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. The collection of information in part 201 has

been approved under OMB control number 0910-0537.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0324]

International Conference on Harmonisation; Guidance on E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes recommendations regarding the context, structure, and format of qualification submissions for clinical and nonclinical genomic biomarkers related to development of drug or biotechnology products, including translational

medicine approaches, pharmacokinetics, pharmacodynamics, and efficacy and safety aspects. The guidance is intended to create a harmonized recommended structure for biomarker qualification applications that will foster consistency of applications across regions and facilitate discussions with and among regulatory authorities.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance:

Federico Goodsaid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2148, Silver Spring, MD 20903-0002, 301-796-1535; or

Jennifer Catalano, Center for Biologics and Evaluation Research (HFM-735), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0706.

Regarding the ICH:

Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory