believes that the applicable entities should be required to find that there is no adverse impact to the Bulk-Power System from the exception and that it is considered in wide-area coordination and operations. Further, we believe that any exception should be subject to further review by the Regional Entity, NERC, and the Commission. This does not necessarily mean that the Regional Entity, NERC, or the Commission should have to approve the exception, but that any of the three could later audit its implementation.

30. In conclusion, while the Commission provides three options for revising footnote 'b' in this Notice of Proposed Rulemaking, we seek comments on the feasibility of the options and on ways in which the options might be improved. In addition, we seek comment on whether there are other ways for NERC to solve the concerns outlined above in an equally effective and efficient manner.

III. Information Collection Statement

31. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.[29] The information contained here is also subject to review under section 3507(d) of the Paperwork Reduction Act of 1995.[30]

32. As stated above, the subject of this NOPR is NERC's proposed modification to Table 1, footnote 'b' applicable in four TPL Reliability Standards. This NOPR proposes to remand the footnote 'b' modification to NERC. By remanding footnote 'b' the applicable Reliability Standards and any information collection requirements are unchanged. Therefore, the Commission will submit this NOPR to OMB for informational purposes only.

33. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE. Washington, DC 20426 [*Attention:* Ellen Brown, Office of the Executive Director, *e-mail: data.clearance@ferc.gov, phone:* (202) 502–8663, or *fax:* (202) 273–0873].

IV. Regulatory Flexibility Act

34. The Regulatory Flexibility Act of 1980 (RFA)[31] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[32] The SBA has established a size standard for electric utilities, stating that a firm is small if, including its affiliates, it is primarily engaged in the transmission, generation and/or distribution of electric energy for sale and its total electric output for the preceding twelve months did not exceed four million megawatt hours.[33] The RFA is not implicated by this NOPR because the Commission is remanding footnote' b' and not proposing any modifications to the existing burden or reporting requirements. With no changes to the Reliability Standards as approved, the Commission certifies that this NOPR will not have a significant economic impact on a substantial number of small entities.

V. Comment Procedures

35. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due 60 days from publication in the **Federal Register**. Comments must refer to Docket No. RM11–18–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

36. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

37. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

38. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VI. Document Availability

39. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

40. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

41. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

By direction of the Commission. Commissioner Spitzer is not participating.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–27624 Filed 10–25–11; 8:45 am]

BILLING CODE 6717–01–P

[29] 5 CFR 1320.11.

[30] 44 U.S.C. 3507(d).

[31] 5 U.S.C. 601–612.

[32] 13 CFR 121.201.

[33] *Id.* n.22.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 610

[Docket No. FDA–2011–N–0719]

Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a review of the ''Bar Code Final Rule,'' under Executive Order 13563, ''Improving Regulation and Regulatory Review.'' The Bar Code Final Rule, which was published in 2004, requires

certain human drug products and biological products to have a bar code. Information submitted can help FDA to reassess the costs and benefits of the rule and to identify any relevant changes in technology that have occurred since it went into effect. FDA is establishing a public docket to receive information relevant to reassessing the Bar Code Rule. This is an opportunity for interested persons to share information, research, and ideas on the need, maturity, and acceptability of alternative identification technologies for the identification, including the unique identification, of drugs and biological products. FDA will use the information received to assess whether the Bar Code Final Rule is achieving its intended benefits as effectively as possible or should be modified.

DATES: FDA will accept both initial comments and reply comments in response to this notice. Initial comments must be received on or before January 9, 2012 and reply comments on or before February 23, 2012. (See the ''Comments'' section of this document for more information.)

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

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: On February 2, 2011, President Barack Obama issued Executive Order (E.O.) 13563, ''Improving Regulation and Regulatory Review'' (76 FR 3821). One of the provisions in the new Executive order is the affirmation of retrospective reviews of existing significant regulations. As one step in implementing the new Executive order, FDA published a notice in the **Federal Register** on April 27, 2011 (76 FR 23520), entitled ''Periodic Review of Existing Regulations; Retrospective Review Under E.O. 13563.'' In that document, FDA announced that it is conducting a review of its existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of and support advances in innovation that have occurred since those regulations took effect. Under E.O. 13563, and under the Department of Health and Human Services' *Plan for Retrospective Review of Existing Rules,* FDA will consider strengthening, complementing, or modernizing rules where necessary or appropriate.

As FDA conducts its retrospective review of regulations, the Agency will take into account the following factors: [1]

- Whether an action will have a positive impact on innovation in an area of public health, safety, or delivery of or access to care;
- Whether the public health benefits of an action have been realized;
- Whether the public or regulated community view modification or revocation of a regulation as important and have offered useful comments and suggestions for change;
- Whether the impact and effectiveness of a regulation has changed or been superseded by changes in conditions or advances in scientific or technological information;
- Whether there are significant, unresolved issues with implementation or enforcement; and
- How long the regulation has been in effect and whether it has been subject to prior reviews.

The first rule FDA is reviewing under E.O. 13563 is the Bar Code Final Rule. The Agency plans to reassess its costs and benefits and to determine if the Bar Code Final Rule should be modified to take into account changes in technology that have occurred since the rule went into effect in 2004.

I. Background

In the **Federal Register** of March 14, 2003 (68 FR 12500), FDA published a proposed rule (Bar Code Proposed Rule) that would require certain human drug product labels and biological product labels to have a linear bar code that would contain, at a minimum, the drug's National Drug Code (NDC) number. In the **Federal Register** of February 26, 2004 (69 FR 9120), the Agency finalized the proposed rule (§§ 201.25 and 610.67 (21 CFR 201.25 and 610.67)). As discussed in the preamble to the Bar Code Proposed Rule, the rule was intended to help reduce the number of medication errors that occur in hospitals and other health care settings (68 FR 12500 at 12501 through 12502). FDA envisioned that bar codes would be part of a system, along with bar code scanners and computerized databases, that would enable health care professionals to check whether they are giving the right drug (in the right dose and via the right route of administration) to the right patient at the right time (*Id.* at 12501).

The events that led FDA to propose requiring bar codes are described in the preamble to the Bar Code Proposed Rule. In brief, medication errors are known to be a serious public health problem and can occur at several points from the time a health care provider prescribes the drug to a patient to the time when the patient receives the drug. The use of bar codes on drug products was expected to significantly reduce medication errors. Bar codes also can complement other efforts to reduce medication errors, such as computer physician order entry (CPOE) systems (where a physician enters orders electronically into a computer instead of writing the order on paper, and subsequently the order can be checked against the patient's electronic records for possible drug interactions, overdoses, and patient allergies) and retail pharmacy-based computer systems that use a bar-coded NDC number to verify that a consumer's prescription is being dispensed with the correct drug. FDA refers readers to the preamble to the Bar Code Proposed Rule should they wish to obtain details on the events, recommendations, meetings, and literature that shaped the proposed rule.

In the preamble to the Bar Code Proposed Rule, the Agency discussed in detail the challenge of requiring the use of linear bar codes, which, while enabling hospitals to buy scanning equipment with the confidence that their purchased equipment would not be rendered obsolete by new technology, could affect future technological innovation (68 FR 12500 at 12508 through 12510). Comments received related to a public meeting on bar coding, presented an array of differing opinions on the issue of whether to require a specific technology (68 FR 12500 at 12508). Given the complexity of the issues, FDA requested in the Bar Code Proposed Rule comment concerning alternatives that could replace or be used in conjunction with the linear bar code such as another symbol, standard, or technology (*Id.* at 12510 and 12529).

In response to the Bar Code Proposed Rule, FDA received comments including those opposing the use of linear bar codes or asking the Agency to consider other technologies or to eliminate any reference to linear bar codes in the final rule. Such comments primarily argued that selecting a symbology or standard would inhibit technological innovation.

[1] Department of Health and Human Services, ''*Plan for Retrospective Review of Existing Rules,*'' pp. 21–22 (August 22, 2011).

Comments opposed to a linear bar code requirement generally advocated the following alternatives: (1) Two-dimensional symbologies, (2) the European Article Number/Uniform Code Council (EAN/UCC) system generally, (3) radio frequency identification (RFID) chips, or (4) no standard or symbology at all (69 FR 9120 at 9136).

Ultimately, FDA determined that, based on data and public comment, a linear bar code requirement was appropriate (Id. at 9137 through 9138). In the preamble to the Bar Code Final Rule, the Agency addressed comments concerning alternatives to the linear bar code and stated that, while it believed that linear bar codes were an established, cost-effective, widely used and easily recognized technology, it also acknowledged that linear bar codes have several disadvantages. For example, linear bar codes may take up more label space than alternative technologies and may encode less data compared to other technologies. Thus, if more data need to be encoded on the packaging or labeling for any other reason (such as to allow tracking and tracing of drug products through the drug distribution system), a linear bar code might prove too limiting (Id. at 9137). FDA also stated that, although it had decided to preserve the linear bar code requirement, it would consider revising the rule to accommodate newer technologies as they become more mature and established (Id. at 9137 through 9138).

Since FDA issued the Bar Code Final Rule, advances in alternative technologies have occurred. In addition, it has become increasingly clear from industry, health care providers, and other FDA initiatives, that certain FDA-regulated products present unique bar coding concerns. For example, the Agency has since learned that certain vaccines present unique challenges 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.[2]

In recognition of these challenges, in the **Federal Register** of August 11, 2011 (76 FR 49772), FDA announced the availability of a final guidance document entitled ''Guidance for Industry: Bar Code Label Requirements—Questions and Answers'' [3]. This guidance amended and superseded the final guidance of the same title dated October 2006, by incorporating a revised response to question 12 (Q12), which pertains to the use of alternate coding technologies for vaccines. The Agency explained in the **Federal Register** notice announcing the final guidance that it believes alternative technology such as two-dimensional symbology has advanced, allowing the Agency to reconsider the use of such technology. Accordingly, it will now 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. FDA limited the scope of its revised response to Q12 to vaccines because of the mandatory reporting concerns specific to these products as described in the guidance.

FDA recognizes, however, that since alternative technologies continue to advance, it may now be feasible for these technologies to address other stakeholder coding needs in other contexts and for other products. For example, under section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355e), FDA is developing standards for identification, validation, authentication, and tracking and tracing of prescription drugs. The goal of this initiative is to implement a system to further ensure patient safety and to improve the security of the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. In March 2010, FDA issued a guidance that discusses a standard for uniquely identifying prescription drug packages using a Standardized Numerical Identifier (SNI).[4] In the guidance, the Agency did not specify the means of incorporating the SNI onto the package. However, the guidance recognizes that the SNI is a flexible standard that can be encoded into a variety of machine-readable forms of data carriers, such as two-dimensional bar codes, alternate coding systems, and RFID. Thus, the guidance leaves options open while technologies for securing the supply chain continue to be identified, and standards making use of SNI are developed. Similarly, while FDA recognizes that the underlying primary goals of the Bar Code Final Rule and section 505D of the FD&C Act are different, the Agency wants to leave options open with respect to how the same technology may be used for both purposes.

FDA is announcing the establishment of a public docket to provide an opportunity for interested persons to share information, research, and ideas on the effectiveness of the current regulation and the need, maturity, and acceptability of alternative technologies for the identification, including the unique identification, of drugs and biological products. FDA will use the information received to assess coding technologies in relation to current bar code requirements and other initiatives.

II. Request for Comments and Information

FDA is requesting comments and supporting information on (1) bar code labeling standards for drugs and biological products and (2) the identification of current alternative technologies for use by industry and others.

To facilitate this discussion, FDA sets forth some questions in the following paragraphs. These questions, which are not meant to be exhaustive, are provided to stimulate public comments that will help FDA evaluate the Bar Code Final Rule and the accommodation of alternative technologies to the linear bar code requirement (§ 201.25). The public is encouraged to address these and/or other related questions.

The Agency encourages responses to the following questions about the costs and benefits of any alternative to the linear bar code. FDA also encourages you to provide as much detail and context as possible in your responses. Furthermore, the Agency specifically invites small businesses to provide information about the potential impact of alternatives to the linear bar code.

1. Is there a need for alternative technologies to the linear bar code? Does the current linear bar code requirement meet the current needs of the health care industry and health care providers?

2. How has product coding technology changed since FDA issued the Bar Code Final Rule on February 26, 2004? Please provide information about the maturity, degree of adoption, cost, and ease of use of coding technologies

[2] The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660) (42 U.S.C. 300aa–25(a)) requires health care providers to report certain adverse events related to identified childhood vaccines to the Vaccine Adverse Event Reporting System (42 U.S.C. 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.

[3] ''Guidance for Industry: Bar Code Label Requirements—Questions and Answers'' dated August 2011 (*http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/UCM267392.pdf*).

[4] ''Guidance for Industry: Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages'' dated March 2010 (*http://www.fda.gov/downloads/RegulatoryInformation/Guidance/UCM206075.pdf*).

that may be considered as alternatives or in addition to the linear bar code.

3. What factors other than those listed in question 2 should FDA take into account in considering technologies alternative to or in addition to the linear bar code?

4. What technologies or coding systems warrant FDA's consideration as alternatives to the linear bar code? In your response, the Agency particularly invites comments on the following issues for each technology identified:

A. What is the current state of development and availability of the alternative technology?

B. Would adoption of this technology as an alternative to the linear bar code further reduce medication errors in hospitals and health care settings? Please provide supporting data, if available.

C. Would adoption of this alternative technology advance public health protections? If so, how? If supporting data exist, please provide this information.

5. Does the adoption of this alternative technology have implications for other FDA or Department of Health and Human Services initiatives (*e.g.,* SNI)?

6. Have you used the linear bar code for authentication or tracking and tracing of prescription drugs?

A. If so, how?

B. Please describe any successes or challenges that you have encountered in adopting linear bar code technology for this purpose.

C. If not, which if any alternative technologies could reduce medication errors while also serving other functions?

7. For hospitals and other health-care facilities that have adopted bar code technologies using linear bar codes:

A. What difficulties did you encounter in adopting the technology?

B. How have productivity and operating costs changed?

C. What differences have you seen in medical outcomes?

D. What problems have you experienced with the technology?

8. For hospitals and other health-care facilities that have adopted alternative technologies or non-linear coding:

A. What difficulties did you encounter in adopting the technology?

B. How have productivity and operating costs changed?

C. What differences have you seen in medical outcomes?

D. What problems have you experienced with the technology?

9. For hospitals and other health-care facilities that have not adopted bar code technologies using linear bar codes:

A. Do you plan to adopt the technology within the next 12 months?

B. If you do not plan to adopt the technology, please explain what factor(s) most influenced the decision not to adopt it.

10. How would technology adoption have proceeded since 2004 had the Bar Code Final Rule not gone into effect?

11. What are hospitals' and other health-care facilities' forecasts for technology adoption once incentives in the Economic Stimulus Act of 2008 (Pub. L. 110–185) are no longer in effect?

12. Would there be an economic impact on those parties who may not be subject to the bar code requirement but who nonetheless may use or adopt or have adopted bar code technology (*e.g.,* hospitals, clinics, public health agencies, and health care providers)? Please use the following questions to guide your responses.

A. *Current practices.* Describe your current practice(s) at your institution with respect to those products that are required to be labeled with a bar code under §§ 201.25 and 610.67. Have you encountered any barriers to your ability to use technology at your institution?

B. *Using an alternative to the linear bar code.* If an alternative to the linear bar code could be placed on the label of at least some of your products, what impact, if any, would that have on your current practice(s)? How would you change your practices, if at all?

C. *Expenses.* What unplanned expenses, if any, would you incur, if an alternative to the linear bar code could be placed on the label of at least some of your products? If you could foresee using an alternative to the linear bar code, would you modify operations in your facility, and if so, how?

D. *Adverse event reporting and recalls.* Have you encountered challenges/successes in drug identification or reporting with respect to products that contain a bar code on their labels? If so, please describe them. Would an alternative to the linear bar code have an impact on your recall management or adverse event reporting, and if so, how?

13. Are there other parties whose economic interests we should consider?

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.

Please allow sufficient time for mailed comments to be timely received by the due dates in the event of delivery delay. Comments must be received by these dates to be considered. We request that comments be identified clearly as an ''initial'' comment or a ''reply'' comment. Initial comments may address any issue raised in this notice. Initial comments will be made available electronically, online at *http://www.regulations.gov,* or for public inspection in the Division of Dockets Management (see **ADDRESSES**). To allow sufficient opportunity for interested persons to prepare and submit any reply comments, late-filed initial comments will not be considered. Reply comments must address only matters raised in initial comments and must not be used to present new arguments, contentions, or factual material that is not responsive to the initial comments. To be considered, reply comments must identify which initial comments they are replying to, and which specific issues(s) are being addressed. We will not consider comments received during the reply comment period that do not identify the specific issue(s) raised during the initial comment period on which the reply comment is based. It is the Agency's intent to comply with Executive Order 13563 as quickly as possible, so we will not look favorably on requests for extensions of the comment period.

Comments previously submitted to the Division of Dockets Management for the following docket will also be considered by FDA and do not need to be resubmitted: ''Draft Guidance for Industry: Bar Code Label Requirements (Question 12 Update)'' (75 FR 54347 September 2010; Docket No. FDA–2010–D–0426).

Dated: October 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–27657 Filed 10–25–11; 8:45 am]

BILLING CODE 4160–01–P