

alternative was \$46.0 million. We did not select this alternative because we could not demonstrate that the added benefits would exceed the added costs.

c. *Covering All OTC Drug Products.* We considered requiring all OTC drug products to include bar coded information. This alternative is currently rejected (although we invite comments on the OTC drugs to be covered) because the additional costs do not appear to be justified by the expected benefits. At this time, most noninstitutional settings are unlikely to have access to bar code reading systems. Therefore, we could not identify any significant reductions in ADEs due to this alternative. Including all OTC drug products would create estimated additional annualized costs to the manufacturing sector of \$1.9 million. The expected annualized costs of the regulation therefore would increase from \$5.1 million to \$7.0 million with no additional quantifiable benefit.

d. *Exemption for Small Entities.* We considered exempting small entities, but rejected the alternative due to the modest projected impact of this initiative on small businesses and the lack of label standardization that would result.

e. *FDA Selecting a Specific Symbolology.* We considered requiring bar coded information with a specific symbolology. The rationale for considering this option was to minimize uncertainty to hospitals in selecting systems that would be able to confidently read the specific language. We decided, however, that identifying a specific symbolology might adversely impact future innovations in other machine-readable technologies. The selected alternative would allow individual facilities and suppliers to devise systems that would maximize their own internal efficiencies, as long as the standardized information could be accessed. The lack of consistent universal standards has been a major impediment to the use of this technology. As long as symbolologies could be read within a single standard, however, the identified market failure would be overcome. In addition, the expected costs of this proposal would be much greater than the selected alternative. Annualized costs to manufacturers would increase to \$8.3 million and significant costs would occur to the retail sector due to the need for accelerated upgrade or replacement of currently installed scanners. Retail pharmacies would incur annualized costs of \$14.4 million. Consequently, we rejected the alternative of identifying a specific symbolology.

3. Outreach

We held a public meeting on July 26, 2002 to solicit comments from the affected sectors. Interested parties from the health care sector, manufacturing sector, retail sector, and equipment suppliers provided comment and insight to the agency. In addition, we met with various industry groups in order to ensure viewpoints were appropriately considered. These insights affected the regulatory considerations, and additional outreach is planned during the regulatory process.

P. Conclusion

We have examined the proposed rule and find that the expected benefits outweigh the costs and that the regulation would improve public health. The detailed analysis that provides references and support for the summary that appears in this section is available in the docket as Ref. 46.

VIII. Request for Comments

In addition to requesting general comments on the proposal, and the specific requests on assumptions contained in the economic analysis, we are seeking comment on the following specific issues identified in the description of the proposed rule (presented here for the convenience of the reader):

1. Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes (see section II.B.2.a of this document).
2. The risks and benefits of including vaccines in a bar code rule (see section II.B.2.a of this document).
3. What terms we should use to describe OTC drugs that should be subject to the bar code requirement (see section II.B.2.b of this document).
4. Information on the costs and benefits associated with putting lot number and expiration date information in the bar code (see section II.C.2 of this document).
5. Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards (see section II.D.1 of this document).
6. Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbolologies (see section II.D.1 of this document).
7. Whether the rule should adopt a different format (whether that format is a symbolology, standard, or other technology), considering the following issues:

- What other symbol, standard, or technology should we consider, either in place of a linear bar code or in addition to it?

- How accepted is that symbol, standard, or technology among firms that would have to affix or use that symbol, standard, or technology?

- Will hospitals be able to read or use the symbol, standard, or technology, either with existing equipment or equipment under development? (see section II.D.1 of this document).

8. Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary (see section II.F of this document). In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?

9. Whether the implementation period for a final rule can and should be shortened from 3 years to some other specific time period (see section II.G of this document).

10. Whether we should require the use of ISBT 128 for blood products, a specific symbolology that is consistent with that required for drugs in proposed § 201.25, or "machine-readable symbols" as approved by the Director of CBER (see section II.H of this document).

11. How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label, and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital (see section II.H of this document).

12. Whether any of the alternatives discussed in the economic analysis have merit (see section VII.O of this document).

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any mailed comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.