Global Regulatory Policy

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Docket No. 02N-0204
Proposed Rule: Bar Code Label Requirement for Human Drug Products and Blood

Merck & Co., Inc. is a leading worldwide human health product company. Merck's corporate strategy — to discover new medicines through breakthrough research — encourages us to spend nearly $3 billion annually on worldwide Research and Development (R&D). Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many of the important pharmaceutical and biological products on the market today.

With the goal of improving patient safety, Merck already voluntarily prints bar codes, including NDC numbers, on the primary labels of 90% of our U.S. pharmaceutical units. Therefore, Merck is very interested in, and well-qualified to comment on, the proposed rule, *Bar Code Label Requirements for Human Drug Products and Blood*, hereafter referred to as the Rule. The text that follows is divided into general comments, questions asked by the Agency, and lastly conclusions.

GENERAL COMMENTS

Merck appreciates the opportunity to comment on the Rule and we acknowledge the careful thought and hard work the Agency put into its drafting. We share the Agency's goal of reducing medication errors via bar coding and we share an unwavering commitment to the highest standards of patient safety.

Merck supports the Rule and its requirement to include an NDC bar code on the immediate container and secondary packaging components. In the spirit of ensuring the most efficient system by which the health care industry may contribute to the goal of reducing medication errors, however, we request that the Agency consider issuing a final rule that is flexible enough to accommodate advancements in technologies, as they become available; this ensures that improvements may be readily adapted without the need for revised regulation. Minimally, the Rule should allow flexibility to select from either linear or two-dimensional bar code symbologies. This flexibility will allow sponsors to consider alternatives when label space is severely limited (e.g. injectable products).

FDA QUESTIONS

We repeat the specific issues identified in the description of the proposed rule below for the convenience of the reader and provide Merck's reply to each.

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).**

Merck supports the Agency's decision to omit prescription drug samples from the proposed bar code rule. The majority of drug samples are not administered in hospitals, rather they are dispensed in clinic and office settings, where the use of bar code scanners is rare. Therefore, the inclusion of bar codes on samples should not be mandated by regulation as the costs do not outweigh the benefits at this time. However, in more technologically advanced settings, bar codes could be utilized to link samples to a given patient, and the inclusion of bar codes on samples may assist sales representatives when accounting for samples. Therefore, sponsors should be permitted to voluntarily bar code samples as is being done by some sponsors today. Merck intends to continue applying the NDC bar code to physician samples.

2. **The risks and benefits of including vaccines in a bar code rule (see section II.B.2.a).**

Merck does not object to the inclusion of vaccines in a bar code rule. However, the inclusion of bar codes on vaccines presents unique challenges making it imperative that the Agency prioritize the best use of labeling space, rather than merely imposing the bar code requirement. Section II.D.2 of this Rule requires not only the bar code, but sufficient blank space around it so that the code may be scanned. This is in addition to existing regulations that dictate the inclusion of labeling statements, where space is already limited. At some point, sponsors may be unable to comply with all regulations. Therefore, it would be beneficial to all concerned if the Agency would consider modifying the small vial labeling requirements in order to accommodate bar coding prior to issuance of the Final Rule. Vaccine manufacturers are willing to meet with the Agency to discuss the unique challenges presented by small vials.

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).**

No comment.

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).**

We agree with the Agency's statement that there is no evidence to suggest the benefit of including lot number and expiration date outweighs the costs.

The costs to industry to include the lot number and expiration date results from the costs associated with the development and installation of on-line printing and verification technology that has not been widely demonstrated at production line speeds of 250-300 units/minute.

The difficulties associated with on-line printing options include:

- Preselecting a lot number and expiration date. Developing printing mats off-line bearing a RSS composite bar code (or equivalent) that would be unique to each packaging run. The preprinted mat would be used on-line to apply the lot number and expiration date.
- On-line printing with the potential to compromise line speed and print quality.

- Limiting packaging options until printing/packaging technology is capable of supporting on-line production speeds and adequate print quality.

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).

The FDA should not restrict sponsors to *linear* symbology. Rather, the standards setting groups should endorse useful symbologies. The Rule should refer to symbologies in a general way, such as *bar codes that are in alignment with standards established by recognized standards setting groups*, such as the Uniform Code Council (UCC/EAN), the Health Industry Business Communication Council (HIBCC), and the American National Standards Institutes (ANSI) *Bar Code Print Quality Guideline*. The Rule should permit flexibility with regard to symbology so that as improvements become available, they may be readily adapted without the need for revised regulation.

Minimally, the Rule should allow flexibility to select from either linear or two-dimensional bar code symbologies. This flexibility will allow sponsors to consider alternatives when label space is severely limited (e.g. injectable products).

6. Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies (see section II.D.1).

We understand that all bar code symbologies, including the recently released RSS linear code and the two-dimensional code, can be read by scanners currently in use. The software is configured in such a way that the scanner can recognize the code type.

7. Whether the rule should adopt a different format (whether that format is a symbology, 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?**

The Rule should permit flexibility with regard to symbology so that as improvements become available, they may be readily adapted without the need for revised regulation. The FDA should not restrict sponsors to *linear* symbology. The final rule should not prohibit the use of more advanced bar codes. Rather, the Rule should refer to symbologies in a general way, such as *bar codes that are in alignment with standards established by recognized standards setting groups.* See our response to Item 5.

Minimally, the Rule should allow flexibility to select from either linear or two-dimensional bar code symbologies. This flexibility will allow sponsors to consider alternatives when label space is severely limited (e.g. injectable products). Merck is actively involved with the Vaccine Identification Standardization Initiative (VISI). VISI recognizes that vaccine vials and syringes, due to their small size, offer significant print challenges. While VISI supports RSS as a viable code for NDC bar coding of small vials, VISI is currently working with the UCC to approve the use of a two-dimensional bar code symbology for vials and syringes.

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

No comment.

- **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).**

We understand that all bar code symbologies, including the recently released RSS linear code and the two-dimensional code, can be read by scanners currently in use. The software is configured in such a way that the scanner can recognize the code type.

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). In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?**

No comment.

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).**

Merck views the implementation period of 3 years as reasonable, given our prior experience in bar coding our products. However, for companies that lack experience with bar coding, 3-5 years may be more reasonable.

10. **Whether we should require the use of ISBT 128 for blood products, a specific symbology that is consistent with that required for drugs in proposed 21 CFR 201.25, or "machine-readable symbols" as approved by the Director of CBER (see section II.H).**

No comment.

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).**

No comment.

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

No comment.

CONCLUSIONS

Merck supports the inclusion of NDC numbers in bar codes on prescription drugs and biologics. We encourage the Agency to build flexibility into the Rule with regard to the symbology of the bar code to minimize the need to revise the regulation in the future. The Rule should refer to symbologies in a general way and delete reference to *linear* symbology. It is premature to include the lot number and expiration date in bar codes at this time as the costs outweigh the expected benefits. The labeling of vaccines and small vials presents unique challenges that are best considered prior to the issuance of a Final Rule.

We appreciate the opportunity to comment and recommend that the Rule be revised to address the points outlined above. We appreciate the collaborative nature of the Agency's efforts to date and welcome the opportunity to meet with you to discuss these issues.

Sincerely,

Lauren M. Hetrick

for David Blois, Ph.D.
Senior Vice President
Global Regulatory Policy