



21 CFR Parts 201, 606, and 610
Bar Code Labels for Human Drug Products and Blood; Proposed Rule

Datamax Corporation Response

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Datamax Corporation is a leading manufacturer of direct thermal and thermal transfer printers, parts and supplies to virtually all industries and companies throughout the world. With over twenty-five years experience in providing printing solutions, Datamax is in a unique position to provide a response to the FDA concerning the proposed rule on the bar code labeling of human drug products and blood and blood components.

Before addressing the FDA's questions, it is important to acknowledge the amount of work that the FDA put into developing this proposal. Datamax was present at the public meeting when this issue was first proposed to the various industries it will ultimately affect. At that meeting, many different viewpoints were expressed and it was immediately clear that this project could not be easily defined by the agency, even though the underlying goal of improving the safety of America's healthcare system was always visible. Datamax would like to thank the FDA for its efforts and is honored to be able to share, through many years of experience in bar coding implementations, a response to the FDA proposal.

Q1. Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes.

Prescription drug samples contain prescription drugs that could potentially interact with patient's current pharmaceutical regimen, or cause adverse allergic reactions. The benefit of requiring bar coding on any pharmaceutical packaging is to set up an infrastructure where system checks can be implemented, whether the physical check occurs in a hospital setting or a physician's office is immaterial. One argument against requiring bar coding on samples is that doctors wouldn't have the technology to utilize the bar code while handing out the sample in their office. From a technology manufacturer's perspective, this argument is becoming less valid as doctors invest in automatic data capture technology to achieve HIPAA privacy and security compliance as well as some of the other benefits that bar coding can achieve such as tracking procedures, lab specimens, radiology files, etc. Most sample packaging is larger than unit-of-use packaging, so incorporating a bar code into this real estate could be less of a challenge for pharmaceutical manufacturers.

From a bar code printer manufacturer's perspective, Datamax understands that incorporating bar coding into product packaging requires a review of all packaging levels, even those not being affected by new regulations. Datamax supports incorporating bar coding onto sample packaging with the understanding that the three-year time frame might be too short for this aspect of the proposal. Much, if not all, of

that three-year time frame will be used to develop the packaging line changes for all other levels of pharmaceutical packaging.

Q2. The risks and benefits of including vaccines in a bar code rule?

Datamax believes that in order for any system to be implemented, all of its components must be addressed. Vaccines are an integral component of the comprehensive health care system in the United States. Vaccines occasionally adversely affect the patients they are administered to, just as incorrect medication, either in dosage, delivery, etc., can adversely affect patients. The advances in bar coding technology, such as the new Reduced Space Symbology – a part of the UCC system – allow for bar codes to be incorporated into even the smallest of packaging levels. Bar coding vaccines will be an important step toward the ultimate goal of an integrated electronic patient health record that chronicles all components of a patient's healthcare elements.

Q3. What terms we should use to describe OTC drugs that should be subject to the bar code requirement?

Datamax defers to the pharmaceutical and healthcare administration experts to answer this question.

Q4. Information on the costs and benefits associated with putting lot number and expiration date information in the bar code?

The advances in bar coding technology now make it possible to incorporate secondary information such as lot number and expiration date into a bar code without taking up large amounts of space. The costs associated with this undertaking are largely made up of packaging production efforts, since many packages are pre-printed in large batches. Requiring lot number and expiration dates to be incorporated into packaging would affect how far in advance pharmaceutical manufacturers could create the packaging, or at least that component of the packaging. Requiring manufacturers to label lot number and expiration date information on the factory line could add significant costs and slow down production lines to the point that overshadows the benefit achieved from adding this information.

One important note on this topic – one of the arguments against including secondary information in the proposal is that this information is not deemed necessary due to the low threat of recalled products. Industry consensus seems to say that this threat is so low because when recalls are issued, pharmacies pull ALL of that product from their shelves, not just the affected lot numbers. So, effective tracking of this information has never really been compiled, making the conclusion of a low threat level premature.

Q5. Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.

It has been shown time and time again that industry accepted standards created and managed by a non-biased party are an integral component of the success of a new technology infrastructure. Standards-based systems, if developed correctly, allow the system to grow and evolve in accordance with changing technology and users' needs. The FDA, while overseeing the labeling of pharmaceutical products, presumably does not also want to assume the management of the technology behind it. Nor should the FDA, as that is what standards organizations such as the UCC/EAN and HIBCC exist for. Omitting mention of any standards system would require the FDA to dictate the bar code structure, essentially replacing the work of the standards organizations.

Q6. Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies.

Datamax defers to the scanning manufacturers to provide feedback on this issue.

Q7. 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?
- How accepted is that symbol, standard, or technology among firms that would have to affix or use that standard, symbol, or technology?
- Will hospitals be able to read or use the standard, symbol or technology with existing equipment or equipment under development?

Datamax believes that all of these related questions are addressed by the FDA adopting an unlimited standard – such as the UCC/EAN system – without limiting the use of that system to only linear bar codes. The UCC/EAN system includes not only linear bar codes, but also two-dimensional bar codes currently being used within many industries. The UCC/EAN system will also be incorporating RFID (Radio Frequency Identification) standards as they become more developed and appropriate for industry applications. These symbologies and standards all work in conjunction with one another to provide a comprehensive automatic identification and data capture infrastructure. Datamax strongly stresses that the FDA should drop the reference to linear in the requirement of the bar coding standards.

Q8. Whether any specific product should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary. In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?

Datamax addresses this question from a technology manufacturer's perspective with extensive experience assisting in the development of comprehensive tracking systems. A tracking system cannot operate at its full efficiencies and will always be at the mercy of human error if there are items within the system that are not incorporated into the technology infrastructure. As stated before in this response, advances in bar coding technology virtually eliminate any size restrictions on incorporating bar codes into

packaging. Therefore, with the goal of improving the quality of the healthcare provided to Americans, Datamax urges no exceptions to the bar code labeling rule.

Q9. Whether the implementation period for a final rule can and should be shortened from 3 years to some other specific time period.

In our extensive experience creating comprehensive automatic identification and data capture systems, Datamax stresses that incorporating this new technology is a time-consuming exercise. The amount of time required for any individual company to undertake this project is really dependent on a review of their entire product line, and all of its associated packaging levels. To ensure that pharmaceutical manufacturers have the opportunity to implement this technology correctly, it is Datamax' position that the time frame should not be shortened. Beyond that, Datamax defers to the pharmaceutical manufacturers to provide feedback on the specific time frames they need.

Q10. 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 §201.25, or "machine-readable symbols" as approved by the Director of CBER?

One of the most difficult aspects of devising an entirely new system is the dizzying array of choices available to a governing agency. In the case of the blood products industry, this challenge is relieved because the industry has already ratified a specific symbology developed specifically for products within their realm. The development of the ISBT 128 standard was undertaken in such a way that ensures that the standard can evolve with the expanding use of technology, and that it can coexist within a traditional UCC/EAN system. ISBT 128 differs from UCC/EAN 128, but all Datamax printers are capable of printing both symbologies, and we would assume that other printer manufacturers have this capability as well. The FDA support of the ISBT 128 symbology would certainly facilitate its adoption worldwide and ensure that this sector of the healthcare industry would continue to be able to effectively track and identify valuable blood products immediately.

Q11. 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 that can properly identify the intended recipient of 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.

Datamax is not a manufacturer of scanning devices, so we will leave the in-depth argument to those better equipped to present it. However, we feel obliged to insert that the FDA's seeming impression that scanners can only decode one type of symbology is misinformed. Scanners today are capable of deciphering many different types of codes and symbologies, the distinction lies in the software that drives the device. It would serve the FDA well to meet with representatives from the scanning industry to better understand the comprehensive capabilities of their technology.



Q.12 Whether any of the alternatives discussed in the economic analysis have merit?

Datamax is in the business of manufacturing thermal printers for printing bar code labels. We leave the discussion of the economic merits to those intimately involved in the manufacture and distribution of pharmaceutical products.