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Date: April 8, 2003

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Dockets Management Branch (HFA-305)
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RE: 21 CFR Parts 201, 606, and 610
[Docket No. 02N-0204]
Bar Code Label for Human Drug Products And Blood; Proposed Rule

Colorcon is a global formulator and manufacturing leader of color film coating systems and state-of-the-art solid dosage imaging technologies for the pharmaceutical industry. Our technologies are used by pharmaceutical companies worldwide to distinguish and protect solid dosage forms, especially tablets.

Colorcon has developed state-of-the-art technologies for tablet and other solid dosage forms in partnership with other leading dosage imaging technology companies. Colorcon and its partners have developed technology that allows a pharmaceutical company to distinguish its tablets and other dosage forms for the purpose of reducing medication errors and to enhance patient compliance.

A relevant new technological development by Colorcon is the commercial ability to print and scan two dimensional (2D) bar codes on color film coated tablets (and other solid dosage forms).

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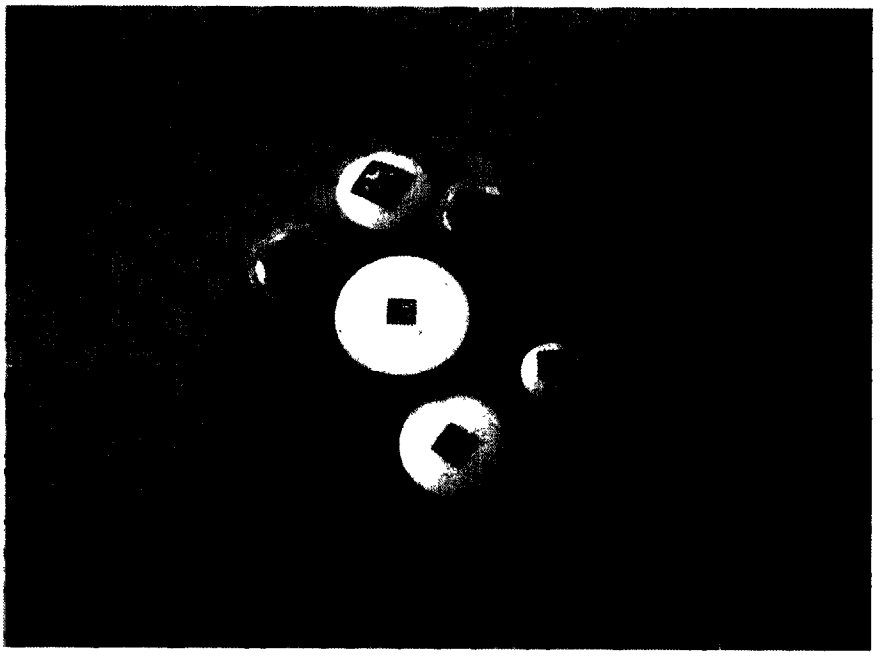


Additionally, Colorcon and its partners have developed the ability to covertly authenticate pharmaceutical dosage forms using pharmaceutical globally approved markers in the form of molecular bar codes. In combination, Colorcon can commercially enable 3D bar coding of solid dosage forms, essentially a covert bar code within an overt bar code.

In combination with unique film coating colorant technology and high definition printing technology, Colorcon can enable commercial use of imaging systems, that when used in combination with the Colorcon 3D bar coding technology, can allow for visual identification, electronic scanning identification, and immediate evidential in-field chemical identification.

All of these technologies are commercially available, and currently employ equipment that is available and largely in use by the pharmaceutical industry and medical community today.

Based upon these commercially available technologies, Colorcon desires to enable the pharmaceutical industry to employ the imaging systems described above as a viable complement or alternative to the bar coding of unit dose packaging as proposed in 21 CFR Parts 201, 606, and 610 Bar Code Label for Human Drug Products and Blood; Proposed Rule. It may be possible to utilize bar coding of the actual dosage forms as a way to minimize the need for certain types of unit dose packaging. This could help to reduce the cost of medications in the hospital environment while still providing the identification controls desired.

With this purpose as our platform, we respond to the following questions in the Proposed Rule.

In Response to Section VIII Request for Comments

Question 5 – Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.

In consideration of the commercial option of bar coding tablets and other solid dosage forms, it is advisable that the Proposed Rule should allow for 2-dimensional (2D) bar codes imprinted on solid dosage forms. It is necessary to utilize a 2D bar code for the following reasons:

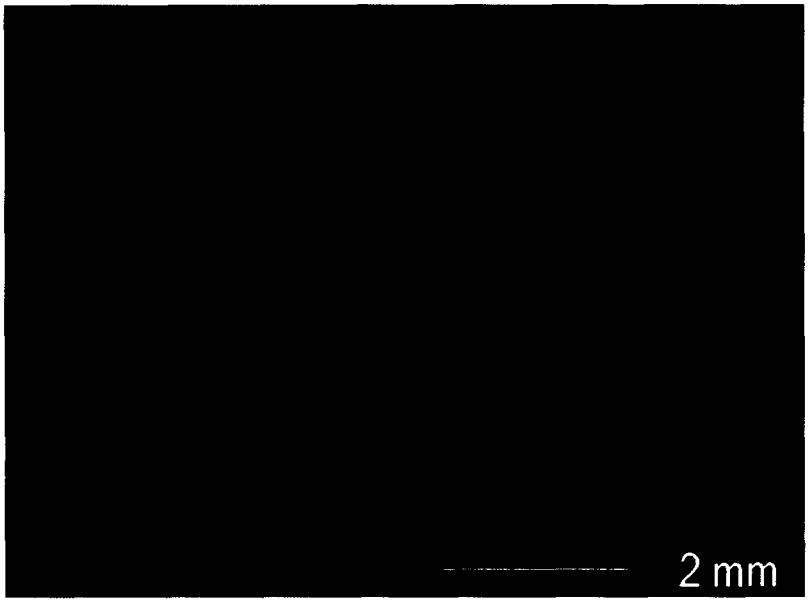
1. To ensure that the NDC number can be contained within the bar code on all solid dosage forms
2. To enhance the elegance of the solid dosage form

Linear bar codes, unlike 2D bar codes, on solid dosage forms cannot accommodate the NDC code due to size limitations on the solid dosage form.

Question 6 – Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies.
Question 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?**
- **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?**

A high-resolution scanner can read linear bar codes, that may be used on unit dose packaging, as well as 2D bar codes that may be used on solid dosage forms. This technology should be considered to enable flexibility to include NDC code information as well as expiration dates and lot numbers if necessary. Commercially available high-resolution scanners are capable of reading both linear and 2D Datamatrix bar codes of 2.5 square mm or smaller commercially imprinted on tablets. Colorcon has shown that it is commercially possible to print on film coated tablets, of various shapes, 2D 2.5 square mm bar codes that include an NDC code.



Additionally, Colorcon has shown that it is commercially feasible to scan a 2.5 mm 2D bar code via a high-resolution scanner. 2D Datamatrix bar codes are robust and readable even when there is only a partial image present on the tablet. 2D bar codes are more reliable than linear bar codes when printed on tablet surfaces. Colorcon has shown that a portion of the 2D bar code within the border could be lost, and still successfully scanned. Hospitals would be able to scan and read both linear bar codes as well as 2D bar codes on tablets with commercially available high-resolution scanners.

In support of enhancing medication safety and reducing medication errors, Colorcon would appreciate the opportunity to present the technologies referenced above and answer any questions related to the commercial capability of applying 2D bar codes to tablets and other solid dosage forms. Colorcon requests to have a meeting with the appropriate parties at FDA to further discuss these options. Please let us know when you think such a meeting could be planned.

Additionally, Colorcon would be pleased to advise the FDA of relevant commercial technologies that are complementary to ensuring the safety of patients and medications through covert evidential authentication and security systems. Such systems, referred to above as 3D bar codes, could be complementary to the safety of all patients by ensuring the authenticity of the drug. This type of technology might also be useful in designing improvements related to Bioterrorism controls.

Colorcon appreciates this opportunity to provide our comments on the identified questions. We plan to make more detailed comments related to the overall proposed regulation at a later date prior to the June 12, 2003 deadline.

Sincerely,

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