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Department of Health and Human Services
Food and Drug Administration

Subject: Response to Proposed Rule
Bar Code Label for Human Drug Products and Blood
DOCKET NO. 02N-0204

Ladies and Gentlemen:

Please accept this response to the invitation for comments on the proposed rule on *Bar Code Label for Human Drug Products and Blood.* For purposes of classification, IntelliDOT Corporation develops and markets healthcare information systems that help ensure the safety of human drug products within the supply chain, including bedside medication verification systems for hospital use.

We would like to begin by commending the initiative and determination with which the Food and Drug Administration has approached the very serious problem of medication errors. Through its efforts, a clear and forceful message has been sent to drug manufacturers, re-packagers, and the healthcare provider industry that change is needed now.

As a participant in the healthcare industry, and hopefully a part of the solution to the need for improved patient safety, we would like to provide comments and additional perspectives that the FDA may find helpful in issuing a final rule later this year. The principals in our company have the benefit of considerable combined experience in hospital pharmacy and nursing, hospital automation, and healthcare systems integration. We hope that you will accept our comments as expert and reasonably objective.

Sincerely,

Gerald E. Forth
President & CEO

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Observations and Comments Concerning the Proposed Rule
We would like to preface our comments with the statement that we are in complete agreement that the medications used in hospitals should carry a machine readable code that can facilitate verification at bedside. This is our business and we are passionate about it.

The FDA is to be commended for giving careful consideration to a variety of constituencies in formulating the proposed rule. In giving careful consideration to hospitals, pharmaceutical manufacturers, and others who have already adopted bar code based packaging and error prevention systems, the agency has shown that it values the innovation that has already taken place in the marketplace. These comments are being submitted in hopes that the FDA will place the same value on innovation yet to be realized. We hope that several small modifications of the proposed rule will provide a pathway for innovation, making the rule itself more effective and accommodating newer technologies as they arise.

To be truly effective, a hospital medication error prevention system must be comprehensive. The presence of bar codes on some of the medications used at bedside will not, in itself, make bedside medication verification a reality. Even after the rule is issued, many drugs will still be packaged in unit dose packaging and labeled on-demand in the hospital pharmacy. It is a simple matter of economics, plus the general belief that fewer drugs will be available in unit dose packaging in the future.

We also believe that the FDA, like any agency that tries to listen to public comment, is somewhat dependent on competing special interest groups for the information needed to make any decision. We believe that one of the reasons for inviting comments before any rule is made final, is to filter out the inevitable errors and misinformation that are accumulated along the way. Our comments will make an attempt to assist with this task.

1. The need for a defined pathway for innovation
We believe that it is self-evident that new technologies can only emerge in an environment where innovation can be rewarded; and where market participants are free to choose new technologies that better meet their needs. In the case of the proposed rule, the selection of linear bar codes as the only acceptable format, leaves no pathway for innovation and the introduction of better ways to solve the problem in the future. This effect needs to be carefully considered. More to the point, the rule does not provide needed direction from the agency as to how emerging new technologies might proceed to gain the approval of the FDA for future use. As will be discussed

in Section 2 of these comments, it would be inappropriate for the EAN or the UCC to assume this role.

In the FCC example used by the FDA staff in making its recommendations, it is noteworthy that the FCC refrained from mandating a specific technology to be employed by manufacturers in order to achieve the goal of DTV reception. In so doing, the FCC wisely avoided the trap of having to serve as the de facto standards board for the industry, reviewing and approving each new leap in technology. What the FCC did, in fact, was to impose a flexible standard on broadcaster transmissions, and then order manufacturers to ensure that their receivers could decode and display the results. In the proposed rule, the FDA has chosen to take a different approach. The goal is a standard identifier (NDC) on all medications, in machine-readable format that may be easily and inexpensively read by a variety of users. This is similar to the FCC decision on mandatory transmission of DTV signals. The FDA has further specified the technology (linear bar codes) that everyone must use. In so doing, the FDA has defined the technology so narrowly (only EAN.UCC sponsored linear bar codes), that other acceptable methods have been excluded. Without arguing the merits of this approach at this point, it then seems both fair and prudent that the FDA also define the pathway for new technologies to receive timely agency review and approval for use on medication labels. This should also include assurances that agency staffing will be adequate to take on this new role. This is consistent with the approach the agency has always taken with respect to new drug and device technologies. To the best of our knowledge, the FDA has never approved a drug or a device, and pronounced that, henceforth, no other innovations would have the opportunity to do the job better.

In the proposed rule, the FDA has specifically said that it would like to encourage new technologies as they become economically available, and the safety and practical benefits are demonstrated. We believe that this goal can only be achieved if the FDA allows new technologies to be applied to medication labeling and tested in the healthcare environment. We recommend that the final rule include very specific guidelines for manufacturers that will allow this to occur, without violating the new regulation.

2. The selection of the Uniform Code Council

We believe that the proposed rule contains material misunderstanding with respect to the nature of EAN.UCC standards, and the substantial powers that the UCC would assume under the proposed rule. By virtue of the narrow definition of allowable bar codes, as those approved and sold by the UCC, we believe that the FDA will be exceeding its authority and inadvertently granting monopoly powers to the UCC. We believe that such a concentration of market power in a single organization is not required to obtain the desired public health benefits, and may, in fact, be a violation of federal law.

First, it is very important to understand that EAN.UCC is not a standards body, and has proprietary interests that prevent it serving in such a role. True standards bodies, such as ANSI (American National Standards Institute) provide an open, defined pathway for the development of voluntary consensus standards; all participants are welcome, so long as they follow a prescribed process for establishing a standard. The UCC has selected a different pathway that involves the support of only proprietary solutions, and the exclusion of others. This last statement is in no way a criticism of the role played by EAN and the UCC in retail commerce; it is a simple fact of how they choose to operate. The UCC is a member of ANSI, and the UPC is an example of a voluntary consensus standard. The UCC is essentially a retail trade association, and as such, cannot be viewed as independent.

The stated mission of the EAN.UCC is *"to provide identification standards to construction of unique and unambiguous numbers that make supply chains more efficient and responsive to customers in any industry."* The UCC performs a very important and appropriate function for its members in this regard. Additionally, the UCC provides sponsored bar codes to members as part of the variable annual fee the member pays. The identification standard itself is the unique numbering system (UPC number or GTIN for example), not the printed symbol that represents it. Virtually all bar code readers in use today can read both UCC-sponsored bar codes and all of the others in common usage. The linear bar codes used on hospital patient ID bands, for example, are not EAN.UCC codes, and do not present a problem to bar code readers in use today. There is no benefit to selecting one linear bar code as a standard symbol. They are all readable with the bar code readers in use today. Although many manufacturers are members of the UCC, many are not. This rule, as written, would require all pharmaceutical manufacturers to join the UCC, and incur unnecessary annual costs related to their use of EAN.UCC standards. Adequate bar code formats are available, at no cost, in the public domain. These free formats are already in wide use in government, education, and manufacturing.

The key to making the FDA proposal work, is to adopt a uniform standard with respect to the unique identifying number, not the specific linear bar code. The use of a uniform numbering system, such as the reformatted NDC will accomplish this goal. The specific bar code to be used does not matter, so long as it is readily readable by the scanners in use today in healthcare settings. The EAN.UCC will always recommend the use of their sponsored bar codes; it is in their economic interest to provide these codes to their customers. But, the FDA cannot be seen as supporting the economic interests of EAN.UCC or any other group. The FDA is interested in an approach to labeling medications that will support the goal of preventing medication errors. This can be done equally well with any bar code that can be read with today's bar code readers, so long as a standard numbering sequence is

followed. This standard number could be the GTIN (EAN.UCC) or simply the NDC identifier currently proposed.

Why would it present a problem for the FDA to specify the use of only EAN.UCC sponsored bar codes? First, it serves no practical purpose. All commonly used linear bar codes can be read by the scanners in use today, without modification. Second, such a decision would allow a single economic entity to control a segment of commerce in the U.S., to the exclusion of all other competitors. Requiring the use of only EAN.UCC bar codes (or those of any particular body, for that matter) is similar to requiring that all PC's use only the Windows operating system, or that only one web-browser be allowed on the Internet, or only one cell-phone communications protocol on all cell phones. None of these examples would be in the public interest and, therefore, would not be permitted under our laws today. In further support of this point, users of UCC sponsored codes pay an annual fee that is related to the sales volume of products carrying UCC codes. This means that the UCC will always have a strong economic incentive to ensure that only UCC sponsored codes will be used on medication labels, and all others are kept out of use. The FDA will have granted the UCC a franchise with significant economic value, and that franchise will be virtually unbreakable. We can think of no other example of an action by a federal agency in modern times that is comparable. The most significant problem will arise as innovation creates new potential solutions, either in printed codes or other means of identifying medications. Who will decide what is acceptable for use in healthcare? In the current proposal, only UCC sponsored codes will be acceptable. This effectively grants the UCC uncontrolled power. Unlike a sanctioned standards body, there are no means for public discussion and no means for appeal of their decisions. Unless the UCC decides to sponsor an emerging technology, it simply will not be allowed into this market. This is monopoly power. It does nothing to improve patient safety, and should not be included in the final rule.

We respectfully recommend that the final rule specify that the identification standard for drug labels is a standard numeric identifier that contains the NDC, as recommended by the FDA. The selection of EAN.UCC sponsored bar codes should be stricken from the final rule, as it serves no useful purpose, and will create an undesirable concentration of power. If the FDA is convinced that a linear bar code is required in order to promote rapid and universal adoption, then a simple statement to that effect is all that will be required. Because of package size limitations, there are about eight bar code formats that are in common use that can meet the requirements. Any of these would be acceptable from the user's perspective. They all look similar and can be read with the same equipment today, without modification. Specification of which bar code formats may be used is not vital to achieving the objective outlined by the FDA and we recommend that it be omitted from the final rule.

3. The case for allowing other code formats (symbols)

The FDA is attempting in the proposed rule, to make a clear case that linear bar codes are adequate for providing the NDC in machine readable code. The most compelling argument is the belief that hospitals would otherwise be faced with incompatible technologies, and might decide not to buy multiple pieces of equipment to read the different codes. In addition, there is also mention of the concern that early adopters of bar code technology might be penalized for their pioneering work, by being forced to replace their equipment. In this section we will respond to these concerns and others. We will attempt to demonstrate that the use of other symbologies on medication packaging will soon become a fact of life, and that the FDA should recognize this and anticipate a time when 2-D codes can painlessly replace linear bar codes. We will attempt to show that patient safety will actually be improved by providing such a transition.

First, and fundamental to understanding this topic, is to recognize that today there are many scanners available that will read both linear 1-D bar codes and the most commonly used 2-D codes. Included within this group are both laser and CCD readers made by a number of companies. Within the next three years, as healthcare becomes a more significant user of machine-readable codes, we can be assured that suppliers of scanning equipment will become very attentive to the needs of this new customer segment. This will mean prices will come down and functionality will increase, as it has in the retail market. The most promising new scanner technology is in digital camera based readers. These scanners have the potential to provide very cheap, highly reliable, and universal reading solutions. Readers with related technology (CCD readers) are already widely used. It is our belief that, well within the three-year implementation window proposed by the FDA, very low-cost optical readers will be widely available, presenting hospitals with even more options for reading all codes. The proposed rule should anticipate these changes, as this will assist hospitals (the 97% without bedside systems) to make the very best buying decisions.

The point of the previous comments is that hospitals are sophisticated buyers of technology. They will buy the technology that offers the highest likelihood of accommodating foreseeable future changes. This reduces the risk of obsolescence. Under the proposed rule, lot number and expiration dates may appear on drug labels in any format the manufacturer desires. This information will not be in linear bar code format, because it will not fit most packages. This information will be in the form of several possible 2-D codes. Hospitals want this information, and if it is available, they will choose technology that will allow them to use it. This will be true whether the hospital has already invested in linear bar code scanners or not. It will be legally indefensible for a hospital to take any other position. Our belief is that

this means that bar code readers with universal reading capability will become the minimum standard in healthcare within a very short time frame.

The case for using linear bar codes is not strong in any case, and becomes weaker still if hospitals will choose to upgrade themselves to more versatile scanners in order to access supplemental lot and expiration date information. This is a critical issue that the FDA needs to evaluate more thoroughly before the final rule is issued. We recommend that the FDA directly solicit comments from major hospitals on this issue. It is widely believed among healthcare providers that ADE's related to recalled lots and expired medications are significantly underreported, because of the nearly impossible task of tracking medications by these parameters once they leave the pharmacy. It is a public health issue of indeterminate size because the currently available data is suspect. The American Society of Health System Pharmacists continues to state publicly that lot and expiration information is essential. The American Hospital Association, Premier and others have also publicly supported inclusion of this supplemental information at various times. Our own market research with hospital pharmacists suggests that the majority of hospitals believe that an effective patient safety system must contain lot and expiration information. We believe that the FDA should defer to the providers of healthcare services on this issue. Lot number and expiration dates can easily be included on drug labels using 2-D codes, and many manufacturers plan to do so voluntarily (Baxter, Pfizer, Abbott). Now, if 2-D codes are going to start appearing on drug packaging anyway, and if used, could also include the NDC as well, why should linear bar codes be used at all?

We understand the sensitivity of the FDA to those hospitals that have already acquired linear bar code readers. The half-life of laser bar code scanners is less than the proposed three-year implementation window. This means that at least half of all scanners currently in use will have been retired and replaced by the time all medications must have a bar code with NDC number. The remaining half will have some useful life remaining, and may be used by hospitals for supply management and other uses. The back-end system that uses the information to track and verify medications is independent of the data acquisition device. This means the hospital's $1 million plus investment in the system itself will not be put at risk. It may not be completely evident at this point in time, but the specification of linear bar codes, coupled with the permissive inclusion of useful information in other formats, will create enormous uncertainty on the part of hospitals. We believe that the only way for hospitals to resolve this uncertainty will be to invest in barcode readers with universal reading capability. The FDA can do much to reduce this uncertainty by including a sunset date in the final rule that effectively allows manufacturers to comply with the labeling requirements with the use of any 1-D or 2-D code after a certain date. All participants will then have a fair opportunity to invest in the technology that will meet the future needs of their institutions.

It is apparent that there are items in use in hospitals today that are too small for even the tiniest of the linear bar codes that can contain the NDC. This includes most vaccines. Every hospital pharmacy has dozens of very small items that are used frequently in patient care. The UCC-sponsored RSS code family can address many small items, but manufacturers we have spoken with have indicated that very small RSS codes (6.5 mil) do not read reliably, and they plan ask the FDA to consider allowing another coding solution for very small items. It is important that manufacturers have a reasonable option other than discontinuing certain dosage forms that cannot be reliably bar-coded. Small 2-D codes provide such an option. Would the FDA reconsider their position if they could be convinced that a number of reasonably priced scanners currently in the market will read both 1-D and 2-D codes?

We are aware of at least two hospitals, Brigham and Womens' in Boston, and Dallas Childrens' Hospital, that have created their own labeling and tracking systems for medications. These hospitals have good reasons for creating their own proprietary systems to address medication errors. They are willing to incur the additional costs of unique labeling and repackaging, in order to ensure that lot number and expiration dates are included in their patient safety systems. In the case of Brigham and Women's, their drug wholesaler supplies medications with correct 2-D codes, applied under GMP, that include NDC, plus lot number and expiration date. It does not seem in the interest of patient safety to force such a system to be abandoned. Under the proposed rule, however, the wholesaler doing the repackaging will be required to cease doing so, because it does not conform to the linear bar code requirement. We believe that it is important, and not at all inconsistent with the patient safety goals of the FDA, that hospitals and their suppliers be permitted to adopt their own solutions to the problem of medication errors. We recommend that the final rule allow manufacturers and repackagers to provide drugs according to the custom requirements of their hospital customers, so long as the NDC identifier is printed on the label in the machine readable format desired by the customer. Once again, there is no obvious public health benefit of doing otherwise.

4. Market Forces vs. Government Intervention

One of the central conclusions of the FDA staff is that market forces, on their own, have failed to provide a solution to the lack of machine readable codes on medications. Furthermore, the FDA has concluded that the industry is unlikely to arrive at a solution within a reasonable time, if given the opportunity. Since this is a matter of opinion, rather than fact, it is difficult to provide helpful comments. However, we hope that these comments will provide another frame of reference.

There is little doubt that the FDA has gained the attention of the entire industry. Voluntary coding of medications, whether due to the FDA's pressure or otherwise, has been accelerating, and about 35% of drugs used in

hospitals are now bar-coded. The marketplace is demanding this and suppliers are responding. In terms of time frame, an exceptional amount of progress has been achieved since April 2001, when Health and Human Services embarked on a serious effort to address this issue. During this same period, 41 states have proposed or passed legislative mandates for hospitals within their jurisdictions that impose medication safety requirements. Hospital groups like HCA, and group purchasing organizations such as Premier and Novation, are now requiring that manufacturers provide packaging with bar codes, if they want to continue doing business with those organizations. There is considerable momentum toward bar coded pharmaceutical packaging, and it is unlikely to stop, even if the FDA does not issue a rule at this time.

Everyone involved in this process, including the FDA, understands that this bar coding proposal carries some risk. Even after this rule becomes final, most hospitals will continue to purchase bulk generic drugs for in-pharmacy packaging and labeling. It is an issue of cost management that will not be solved by this rule. In addition, there is considerable concern on the part of the ASHP and others, that a number of currently available dosage forms will quietly disappear from the market. This will create new safety issues that will need to be addressed within hospitals. There is additional concern that this rule will result in manufacturers exiting the unit dose packaging market, instead pushing the packaging and labeling responsibilities onto the hospital. These are all genuine concerns that will reduce the effectiveness of the proposal.

We believe that the FDA may be able to mitigate these risks if it is willing to be more flexible in implementing this proposed rule. For example, allowing the use of small 2-D codes on very small items, or as a supplement to linear bar codes on all items for that matter, will not prevent the achievement of the desired public health benefits. Over time, the marketplace should be allowed to decide which types of codes best meet the needs of healthcare. If the rule is written with some additional flexibility, the FDA will not need to be involved at all as this market transition takes place.

Finally, we believe that the FDA needs to allow room for the healthcare industry to play a role in defining the standards they will use to implement the proposed rule. The simple act of requiring the NDC in machine readable format, on all medication packaging by a certain date, forces manufacturers and providers to resolve how this will be done. And they will. While the FDA can certainly put itself in the middle of this process, it is not efficient for it to do so. A couple of decades ago, the Uniform Code Council was formed by grocers to solve a pressing productivity problem. Their unanimity caused large consumer product companies to join as well. Within a relatively short period of time, the UPC format was created and now provides an efficient way for commerce to occur in that sector. We believe that under a simplified, but mandatory labeling rule, the same outcome will be achieved in the

pharmaceutical industry. Perhaps the industry needed the kick start provided by the FDA. Now it is time to let the industry do the rest of the work. All the components of an efficient system are available in the marketplace today. We believe that the FDA should monitor the progress toward compliance, but should not manage it.