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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

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

Dear Sir or Madam:

On behalf of Applied Digital Solutions ("ADS"), I am providing these comments on the notice of proposed rulemaking published in the Federal Register on March 14, 2003. 68 Fed. Reg. 12500. The proposal would establish a new requirement that human drug product labels and biological product labels have bar codes that would contain the National Drug Code ("NDC") number for the particular product. The purpose of the proposed rule is to reduce the number of medication errors in hospitals and other health care institutions.

ADS is a small business that is focused on developing advanced digital technology products including implantable personal identification microchips, miniaturized power sources, and security monitoring systems combined with the comprehensive data management services required to support them. ADS applaud FDA's efforts to use machine readable technology as a means of preventing patient injury as a result of medication errors. However, ADS strongly disagrees with FDA's proposal to restrict the technology to linear bar code symbology.

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One of the products ADS markets is the VeriChip™. The VeriChip™ is a small (approximately 11 mm x 2.1 mm (0.3 in. x 0.08 in.) implantable passive radio frequency transponder circuit that weighs approximately 0.6 gm (0.02 oz.). The Verichip™ is inserted subcutaneously into a person, usually in the rear of the upper arm, to provide secure identification. The VeriChip™ is currently marketed for security, financial and personal identification applications. For example, the Verichip™ is used to identify a person, such as a lost child or elderly adult, through the use of an inexpensive small, hand held, battery-powered scanner that reads the identification number on the chip. ADS maintains a database to provide individual identity information and verify access to personal identifying information. The Verichip™ technology is also used in animals. To date, over 30 million animals have been implanted with similar RFID tags.

The VeriChip™ also has potential medical applications. ADS is working with FDA on the appropriate regulatory requirements for these medical uses.

The radio frequency identification ("RFID") technology used in the Verichip™ is simple in its application and is effective in identifying individuals and animals in a cost efficient manner. This technology could easily be adapted as an alternative to or complement the linear bar code symbology that FDA has proposed to require for human drug and biological products. In its proposal, however, FDA rejects the use of RFID technology even though FDA states that "other technologies may be able to encode more data or be more versatile compared to linear bar codes." 68 Fed. Reg. at 12509. FDA does this because, supposedly, according to FDA, "the costs associated with RFID tags and readers could be significant." Id.

The FDA's concerns are misplaced. RFID technology is not only easy to use, in many forms it is inexpensive. The pharmaceutical industry and healthcare providers should be permitted to have the flexibility to select identification technologies most suited to the particular product or clinical setting. It may be entirely appropriate to incorporate several forms of identification to implement

the intent of the proposed regulations. HIPAA regulations must also be considered when structuring a patient identification system.

More important, prescribing a particular technology to the exclusion of other equally effective technologies is inconsistent with the principles underlying other FDA regulations. For example, FDA's regulations on good manufacturing practices ("GMPs") for both drugs, 21 C.F.R. Parts 210 and 211, and medical devices, 21 C.F.R. Part 820, are designed to be flexible. They do not require particular equipment to be used to manufacture a pharmaceutical or a medical device. Rather, the regulations use words like "adequate," "suitable" and "appropriate" that permit the manufacturer the flexibility to design its own manufacturing system to achieve the desired goal of producing safe and effective products. Similarly, here, FDA should not be overly prescriptive and require one technology to be used over others that can produce the same results at equivalent or lower costs. While we do not question that bar code technology is <u>one</u> way of identifying drug products to help reduce medication errors, it is not the only way of doing so, nor is it necessarily the best way. Moreover, by freezing technology in this manner, FDA is creating a disincentive to industry to produce even more cost effective identification systems.

For the above reasons, ADS commends FDA's proposal to require that human drugs and biologics contain the National Drug Code as a means of reducing medication errors in hospitals and other health care settings. On the other hand, ADS strongly objects to FDA's proposal to require only linear bar code technology and to prevent the use of competitive technologies such as RFID.

Sincerely,

Richard F. Seelig, M.D.

Vice President Medical Applications