Novation Comments to FDA's Proposed Rule: Bar Code Label Requirement for Human Drug Products and Blood

12 June, 2003

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

Dear Sir or madam,

Novation greatly appreciates the opportunity of working with the FDA on the bar coding initiative over the last eighteen months. We believe that the agency's March 13th proposal represents a balanced, logical and manageable way for suppliers of pharmaceutical products to include bar coding, and to subsequently assist health care providers in decreasing the numbers of medication errors and mix-ups. Novation is also grateful that representatives from the agency have carefully weighed the advice of all contributors.

Novation is the supply company of two large not-for-profit hospitals alliances, VHA and University HealthSystem Consortium, or UHC. These alliances represent more than 2,300 community-based health care organizations and academic medical centers, ranging in size from a 20-bed rural facility to a multi-thousand bed teaching institutions. We estimate that the two alliance memberships combined represent roughly 30% of the occupied beds in the country. In 2001, VHA and UHC health care facilities chose to purchase some $17.6 billion through Novation agreements.

Our role at Novation is to help the hospital members of VHA and UHC realize efficiencies and cost savings in their purchasing functions. With significant involvement and input by these member hospitals, we negotiate contracts on their behalf for high-quality, cost-effective, and safe products, including commodity products, medical devices and pharmaceuticals. These products and suppliers are chosen through a competitive bidding process and with the advice and consent of advisory panels – actual employees of the member hospitals in areas of specialty such as materials management, nursing, pediatrics, oncology and pharmacy.

VHA and UHC member hospitals constantly bring to Novation's attention that selection of safer products and prevention of label mix-ups and medication errors are key activities in their facilities. Therefore, we have responded. As part of our

- Healthcare Distribution Management Association (HDMA)
- Healthcare Leadership Council (HLC)
- Institute for Patient Safety (ICPS)
- National Alliance for Health Information Technology (NAHIT)

Similarly, although Novation was a fully supportive and participating member of these groups' meetings, and has signed off on their proposals to FDA, our commentary may be slightly different. Be assured that there is no material difference in our goals.

Also, where appropriate in the suggestions/comments to follow, we have referenced the ideas embraced by one or more of the four groups above.

Please note that Novation is pleased with the March 13th proposal, and believes that it could be certified in its entirety "as is". Therefore, any suggestions/comments listed below should not be viewed as negative criticisms, but rather as additions or enhancements for consideration.

RESPONSES TO QUESTIONS 1 THROUGH 12

FDA Question number 1:
Should the rule require bar codes on prescription drug samples and if so what are the costs/benefits of their inclusion (reference the FDA Proposed Rule, Section II.B.2.a.)?

Novation Suggestions/Comments:

Although not often found in hospital settings, samples could in fact be used there. Novation does not feel that requiring bar codes on samples is critical at this time, but encourages the pharmaceutical industry to consider the inclusion of these codes as the technology progresses. We also suggest that FDA continue to evaluate inclusion of bar codes on samples in future discussions and legislation. Novation certainly recognizes that the packaging of samples with bar codes may present some unique technical difficulties, delays and cost additions to suppliers. Based on these observations, Novation concurs with the FDA that drug samples should not be covered by the rule at this time.

FDA Question number 2:
What are the risks and benefits of including vaccines in the rule (reference the FDA Proposed Rule, Section II.B.2.a.)?

Novation Suggestions/Comments:

Novation agrees with the inclusion of vaccines in the final rule for bar code labeling, but is sensitive to the needs of our member hospitals for vaccine products, especially when those suppliers choose to cease or cut back production. Novation therefore agrees with ICPS and HDMA in recommending a separate process be followed for vaccines, in which the vaccine industry is engaged to resolve the issue of supplying this information (both primary and secondary data), for publication in the final rule. We believe that this is a workable solution, since the vaccine industry is very small and therefore easily assembled for discussion purposes and already has a forum under which this issue can be addressed and resolved, namely the CDC's VISI. Vaccines have very particular issues regarding container / label space, manufacturing and cost issues that would best be resolved through direct discussions. This process could be commenced immediately with affected stakeholders and other interested and appropriate parties, with the goal of resolving technical, cost and timeframe issues in a timely manner for inclusion in the final FDA rule to be issued by the end of 2003.

FDA Question number 3:
Are the terms used to describe the Over-the-Counter (OTC) drug product covered by the rule sufficient (reference the FDA Proposed Rule, Section II.B.2.b.)?

Novation Suggestions/Comments:

Novation feels that the wording in this section was slightly confusing and could be further honed, especially from an enforceability viewpoint. Novation agrees with NAHIT in suggesting that the phrase "over-the-counter drug products that are dispensed under an order" be changed to "non-prescription drugs used therapeutically pursuant to a "rescuer's order." Additionally, define the term "commonly used in hospitals" as packaged for hospital use, labeled for hospital use, or marketed, promoted, or sold to hospitals.

FDA Question number 4:
Should the Lot Number and Expiration Date be included in the rule and if so what is the data on the costs and benefits that would justify their inclusion (reference FDA Proposed Rule, Section II.C.2.)?

Novation Suggestions/Comments:

We urge FDA to consider requiring the inclusion of lot numbers and expiration dating in the bar code when the technology is more widely available, and when the end users are more universally prepared to read and scan these new technologies within their institutions. Certainly inclusion of the lot number and expiration date will be benefit end users when tracking outdated

or recalled products. Novation supports this inclusion and asks the FDA to address it as soon as technically feasible.

The addition of lot number and expiration dating in the bar code on product packaging is a very low priority at this point, especially on the smaller unit dose packages where space is extremely limited. With only 1% of hospitals using bar coding at the patient level (or bed side), to get the NDC number added universally would be a huge accomplishment from the perspective of safety enhancement and prevention of medication errors.

As stated above, Novation has worked closely for the last eighteen months with many organizations strongly interested in the bar coding initiatives; all have recommended that we table the issue of adding lot number and expiration dating in the bar code until we see some advances in adding the bar code with the NDC number. We agree with the FDA's wording that accompanied the March 13th proposed rule:

"FDA's proposed bar code rule does not require that the lot number or expiration date be encoded on product packaging because it has not been shown to be cost effective."

"Based on the evidence we had and our obligation under Executive Order 12866 to choose regulatory approaches that maximize net benefits, the potential burden of encoding lot number and expiration information appeared to outweigh the potential benefit at this time." the proposed rule states."

"The emphasis on cost-effectiveness is an early indication of how FDA Commissioner McClellan's background in health economics could affect agency regulations."

"The rule notes that a review of FDA's adverse event reporting system found 90 cases out of 71,546 in which patients received an expired drug and 21 cases in which patients received a recalled drug."

"While lot number and expiration date information would make it easier to identify drugs that had been recalled or were expired, we neither found nor received data to show that the benefits of bar coding lot numbers and expiration date information would exceed the costs of putting that information on the bar code," the proposed rule states.

"A comment from a drug company predicted that encoding lot number and expiration date information would reduce packaging line speed by 40% and cost more than $4.8 mil. For its production lines."

A huge concern to Novation (and the multiple organizations with whom we worked) is that, if the requirements are to onerous, and suppliers are forced to

add lot number and expiration dating, they might choose to discontinue packaging schemes such as unit dose. Of course this would have very negative implications to the end user.

Certainly if companies want to (and are able) to add lot number and expiration date, we would urge them to do so, but only if there would be no price increases that would have to be passed on to our member hospitals.

FDA Question number 5:
Should the rule refer to linear bar codes without mentioning any particular standard (reference FDA Proposed Rule, Section II.D.1.)?

Novation Suggestions/Comments:

Like FDA, Novation has serious concerns that technologies/standards not be so advanced that hospitals are then unable to read and scan the bar codes. This is especially pertinent when one considers the low numbers of hospitals that are now able to use bar coding at patient bedside, by many estimates less than one percent. Novation urges FDA to evaluate and promote new and emerging technologies such as radio frequency, dot matrix, 2D or NSS, but only as they become more readily available, and easily embraced by end users. In the near term, however, the FDA should not require the application of bar codes beyond the scope of one-dimensional symbologies that conform to current HIBCC or UCC/EAN. Many applications of the currently used linear systems are appropriate for suppliers and end users alike.

FDA Question number 6:
What are the current state of bar code scanners and their ability to read various hymnologies (reference FDA Proposed Rule, Section II.D.1.)?

Novation Suggestions/Comments:

Novation agrees with the comment as provided by HLC: Virtually all bedside bar code scanners currently employed in hospitals can read 0or can be programmed to read any linear bar code, and some can read more complex codes. It is our belief that manufacturers will initially use linear bar codes on their packages, given the greater prevalence of linear bar code readers in hospitals. The incentive for manufacturers to use more complex bar codes largely relates to the space on the package, which may be too small for a linear bar code, thus requiring an RSS or two-dimensional bar code. If certain FDA allowances are made for especially small or otherwise difficult-to-bar-code packages, it is less likely that manufacturers will need to resort to more complex bar codes that may require hospitals to purchase new bar code scanning equipment.

FDA Question number 7:
Should the rule adopt a different format for the machine-readable code; what should that format be; how widely is it accepted by the industry; and will hospitals be able to read it with existing equipment or equipment under development (reference FDA Proposed Rule, Section II.D.1.)?

Novation Suggestions/Comments:

Novation encourages the FDA to have enough flexibility in the rule to encourage the adoption of improved auto identification technology as it develops. Again, our desire is to ensure that suppliers will not find the rules to onerous so that they might discontinue or cut back on manufacturing capabilities, and that some of the more rudimentary hospital bar code scanners and readers not be eliminated. By referencing a class of standards such as UCC/EAN rather than a particular technology or format, the FDA can provide for such flexibility in the rule.

FDA Question number 8:
Should there be specific product exemptions from the rule and how should they be defined?

Novation Suggestions/Comments:

Novation does not believe that any exemption for particular products or class of products should be endorsed. All NDC numbered products should face the same standards and scrutiny. Novation DOES recommend that the agency consider relaxing the rules surrounding human readability requirements, especially in the extremely small containers. If there were more space available on small labels, the supplier and end user would benefit from added flexibility.

FDA Question number 9:
Is the implementation timeframe of three years appropriate or can it be shortened; should there be a different timeframe for new drug products (reference FDA Proposed Rule, Section II.G.)?

Novation Suggestions/Comments:

Novation understands the time line given by FDA and feels that this should be ample time for any supplier to gain compliance. Novation's requirements are stricter, however, and we will require that all contracted suppliers apply machine readable bar coding at unit of use by 2004.

FDA Question number 10:
Should the ISTB-128 standard be adopted for blood or should an UCC/EAN standard be required (reference FDA Proposed Rule, Section II.H.)?

Novation Suggestions/Comments:

Novation concurs with NAHIT in requiring a standard for the bar coding of blood products that is recognized by the field and that could be read by the same scanning technology employed in the medication use process. NAHIT recommends that this standard be the ISBT-128. By adopting the standard and requiring it within three (3) years of the final rule, the FDA will move the field forward with compliance to standards with which there is already voluntary consensus.

FDA Question number 11:
How will the rule for blood affect hospitals purchasing decisions for bar code technology given the requirements in the rest of the rule for drug products (reference FDA Proposed Rule, Section II.H.)?

Novation Suggestions/Comments:

Again, per NAHIT: By adopting the ISBT-128 standard, the FDA will promote the scanning of blood products with the same bedside scanning technology used for human drug products. Since current UCC/EAN standards and the ISBT-128 standard are linear codes, scanners now used in hospitals can recognize both.

FDA Question number 12:
Are any of the alternatives discussed by the FDA in the economic impact section of the rule, of issuing no rule or requiring additional information in the code, viable (reference FDA Proposed Rule, Section II.O.)?

Novation Suggestions/Comments:

Novation has no comment on this section, as we have not considered economic impact data in this project.

CONCLUSION:

Novation joins the many other groups with whom we have worked in thanking the FDA for its thorough work in completing this important proposal. We are

member driven philosophy, Novation has launched a comprehensive safety initiative including the requirement for machine-readable bar codes at unit of use.

Novation has worked with all of these groups listed below, and is united with them in thanking the FDA for its insight:

- American College of Healthcare Executives (ACHE)
- American Health Information Management Association (AMHS)
- American Health Packaging
- American Hospital Association (AHA)
- American Society of Health-Systems Pharmacists (ASHP)
- Association of American Medical Colleges (AAMC)
- Catholic Health Association (CHA)
- Coalition of Healthcare e-Standards (CHeS)
- Consorta Catholic Resource Partners
- US Food and Drug Administration (FDA)
- Harvard Risk Management Foundation
- Healthcare Alliance Packaging Council
- Healthcare Distribution Management Association (HDMA)
- Health Industry Business Communication Council (HIBC)
- Healthcare Leadership Council (HLC)
- Institute for Patient Safety (ICPS)
- Institute for Safe Medical Practices (ISMP)
- Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)
- Medical Group Management Association
- National Alliance for Health Information Technology (NAHIT)
- National Business Coalition on Health
- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)
- Occupational Safety and Health Administration (OSHA)
- Premier
- Uniform Code Council (UCC)
- Veterans Administration (VA)

Each of these groups has multiple stakeholders, but we all share the same desire to enhance patient safety and prevent medication errors and mix-ups. Although we were all united in our aim at promoting unit of use bar coding to prevent mix-ups and medication errors, and our goals were universally the same, some of the exact suggestions or comments to FDA on each of the twelve questions might be slightly different.

Novation personnel served as part of a working group and worked very closely with four of the organizations listed above:

especially appreciative of the FDA's listening, and appropriately responding to, the logistics, challenges, and opportunities involved with this project.

As a representative of America's leading hospitals, safety, quality patient care and good stewardship of resources are the top priorities of the hospitals and health care professionals we serve. Their passion, commitment, and insight are transferred to us through their involvement in everything we do as a company. Bar coding at the unit-of-use level is one way we, as a group, can help America's hospitals achieve their healing missions.

SUMMISSION:

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12 June, 2003

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COMPANY/HCO: FDA (Docket No. 02N-0204)

FAX NUMBER: 301/827-6870

DATE: 6-12-2003

FAX NUMBER: 972/581-5033

TOTAL PAGES 10 (Including Cover Page)

COMMENTS: Comments on bar code regulation.

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