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REMARKS BY RONALD BARENBURG, SR. V.P.  
OF  
BARCODE TECHNOLOGY, INC.,  
IN RESPONSE TO THE  
FOOD AND DRUG ADMINISTRATION  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
ON  
BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG  
PRODUCTS

JULY 26, 2002

GOOD AFTERNOON. MY NAME IS RON BARENBURG, SENIOR VICE PRESIDENT OF BARCODE TECHNOLOGY, INC. OR "BTI". SOME OF YOU MAY KNOW US AS INTERNATIONAL BARCODE, WHICH IS OUR PRIOR NAME.

BTI SPECIALIZES IN PROVIDING BAR CODE SOFTWARE AND HARDWARE SOLUTIONS.

THROUGH OUR SUBSIDIARY, SNX, WE HAVE PROVIDED AND SERVICED **BAR CODE PRO SOFTWARE** TO OVER **120,000 CLIENTS WORLDWIDE OVER THE PAST 13 YEARS.**

BTI'S OFFICES ARE LOCATED IN AND NEW YORK CITY AND CORAL GABLES FLORIDA.

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THANK YOU FOR GIVING BTI AN OPPORTUNITY TO ADDRESS THE FDA AND THE HEALTHCARE COMMUNITY ON THE **NEED FOR EXPERT INFORMATION CONCERNING REDUCED SPACE SYMBOLOGY BAR CODES.**

THESE BAR CODES CAN ENCODE **THE NDC, OR NDC, LOT AND EXPIRATION DATE,** ON VARIOUS PACKAGING LEVELS OF PRESCRIBED AND/OR OVER THE COUNTER MEDICATIONS.

LADIES AND GENTLEMEN, OVER THE PAST ONE AND ONE HALF YEARS I HAVE TRAVELED WELL OVER 100,000 MILES TO VISIT **MANY OF THE PHARMACEUTICAL COMPANIES HERE TODAY.**

MANY OF YOU ARE BTI'S CLIENTS, **AND YOU ARE THE TRUE VISIONARIES.** YOU HAVE NOT ONLY SEEN THE VALUE OF REDUCED SPACE SYMBOLOGY AS AN ASSET IN IMPROVING PATIENT SAFETY, **BUT AS A SIGNIFICANT TOOL FOR PRODUCT CONTROL AND TRACEABILITY.**

IN AUGUST OF 2001, UNDER THE GUIDANCE OF THE UNIFORM CODE COUNCIL, **BTI'S SOFTWARE PROVIDED THE RSS BAR CODE GRAPHICS** ABBOTT LABORATORIES USED TO PRINT LABELS ON SMALL VIALS AND AMPOULES. THESE RSS, NDC LABELS WERE THEN SCANNED AT BEDSIDE AT ST. ALEXIUS HOSPITAL IN BISMARK, NORTH DAKOTA. **THIS WAS ONE OF THE FIRST SUCCESSFUL PILOTS OF RSS ON SMALL UNIT-OF-USE PHARMACEUTICAL PRODUCTS.**

SINCE THAT TIME WE HAVE COME A LONG WAY.



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**TWO DAYS AGO, ON JULY 24<sup>TH</sup>, ABBOTT LABORATORIES ANNOUNCED THAT 'THEY PLEDGED TO AFFIX UNIT-OF-USE BAR CODES TO ALL OF ITS HOSPITAL INJECTABLE PHARMACEUTICALS AND IV SOLUTIONS PRODUCT LINES BY EARLY 2003. APPROXIMATELY ONE-QUARTER OF ABBOTT'S INJECTABLES AND IV SOLUTION PRODUCTS WILL USE RSS.**

**RSS IS CURRENTLY IN USE BY OTHER COMPANIES IN THE HEALTHCARE INDUSTRY. ITS SMALL SIZE, POWERFUL ENCODING CAPABILITIES AND HUMAN READABLE FORMATS, MAKE IT IDEAL TO PRINT MACHINE-READABLE INFORMATION ON UNIT-OF-USE, OVER THE COUNTER AND PRESCRIBED MEDICATIONS. AND, IT IS PART OF THE GLOBAL UCC/EAN FAMILY OF BAR CODES, ENSURING WORLD-WIDE ACCEPTANCE AND USE.**

**AS ITS FULL POTENTIAL IS REALIZED, RSS WILL ALSO BE A SOLUTION FOR ENCODING INFORMATION TO AID IN RECORD TRACKING, AND TO PROVIDE PORTABLE DATABASES ON MEDICAL/SURGICAL AND BLOOD PRODUCTS.**

**RSS BAR CODE CAN REPLACE THE HUMAN READABLES CURRENTLY PRE-PRINTED ON LABELS WITH A MINIMUM OF EFFORT AND COST, ENCODING THE NDC NUMBER WITH ACCOMPANYING HUMAN READABLES.**



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AS FOR THE **CRITICAL STEP** OF PLACING LOT NUMBERS AND EXPIRATION DATES ONTO PRODUCT VESSELS **IN REAL TIME**, **ON THE MANUFACTURING LINE**, BTI AND IT'S STRATEGIC ALLIANCE PARTNERS, DOMINO AMJET AND ZEBRA TECHNOLOGIES, HAVE ALREADY DEMONSTRATED TO MANY OF YOU, THE CAPABILITY OF INK-JET AND THERMAL IN-LINE PRINTING AT LINE SPEEDS, WITH LASER PRINTING IN THE NEAR FUTURE..

VERIFICATION PROVIDER, WEBSCAN, ANOTHER BTI STRATEGIC ALLIANCE PARTNER, **HAS "OFF THE SHELF" AND READILY AVAILABLE VERIFIERS** TO PROVIDE ANSI GRADE REPORTS ON RSS GENERATED BAR CODES.

SYMBOL AND HAND HELD SCANNERS HAVE BOTH ANNOUNCED **SUBSTANTIAL SALES OF RSS ENABLED SCANNERS**, WHICH CAN ALSO READ ALL THE **CURRENT SYMBOLOGIES IN USE BY HEALTHCARE TODAY**. JUST AS IMPORTANT IS THE **RSS UPGRADE METHODS AVAILABLE FOR EXISTING SCANNERS**.

THIS SHOULD PROVIDE A **COMFORT LEVEL** THAT WHEN PHARMACEUTICAL COMPANIES ENCODE INFORMATION IN **RSS TO REDUCE MEDICAL ERRORS**, END USERS WILL HAVE SCANNERS THAT ARE AVAILABLE TO READ THAT INFORMATION.

WE LOOK TO THE FDA FOR THE FOLLOWING:

**FIRST**, TO ESTABLISH A BAR CODE SYMBOLOGY STANDARD, LIKE **RSS**, THAT HAS **SOFTWARE THAT IS READILY AVAILABE AND IN USE BY HEALTHCARE TODAY**. A BAR CODE THAT IS



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**EASILY SCANNED BY OFF THE SHELF, READILY AVAILABLE SCANNERS.**

**SECOND, TO PROVIDE FOR AN AGGRESSIVE, BUT REALISTIC TIMEFRAME FOR ADOPTION OF THIS NEW BAR CODING REQUIREMENT.**

**THIRD, TO ESTABLISH MINIMUM, MACHINE-READABLE INFORMATION REQUIREMENTS, WITH IMPLEMENTATION OF NDC, LOT AND EXPIRATION DATE ON THE FASTEST POSSIBLE TIME TABLE.**

**LET US NOT FORGET THE LARGER PURPOSE OF OUR WORK HERE TODAY. BTI, MACHINE-READABLE BAR CODED INFORMATION AND GLOBAL STANDARDIZATION WILL SAVE LIVES.**

**THANK YOU.**