

ScriptPro®

Pharmacy Automation

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Statement on

BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS

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President and CEO
ScriptPro
Mission, KS**

July 26, 2002

**Submitted to
Food and Drug Administration**

Docket No. 02N-0204

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From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
Bar Code Label Requirements for Human Drug Products
July 26, 2002, from 9 a.m. to 5 p.m.
Natcher Auditorium, Building 45
National Institutes of Health, Bethesda, MD

**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON
BAR CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
BIOLOGIC PRODUCTS**

I. Background

ScriptPro develops and provides dispensing automation and robotics for pharmacies. We are dedicated to helping pharmacies lower operating costs, reduce dispensing errors and increase customer service.

We have focused on those pharmacy dispensing settings where the largest number of prescriptions are filled: community and ambulatory pharmacies. These settings involve people working to execute health-critical tasks accurately, at a fast pace and typically in small spaces close in proximity to the general public.

Our systems are operated to a large extent by bar code scanning. Bar code scanning provides a level of efficiency, accuracy and speed that would otherwise not be possible. These systems are user-tested and being used by thousands of pharmacists and pharmacy technicians every day in every type of community and ambulatory pharmacy setting.

In maintaining the databases for our systems, we work extensively with drug products and their bar codes. ScriptPro's research laboratory has samples of most of the drugs and related medical supplies that are dispensed in community and ambulatory pharmacies across the United States.

Bar code labels for drug products are required for efficient and accurate pharmacy dispensing systems. We certainly support initiatives that will provide more and better bar code information for drugs. However, there are serious shortcomings and errors inherent in the drug product bar codes that we have on drug products today. We should develop and execute a plan for fixing these problems in conjunction with expansion of the use of bar codes. If we do not, we will create an even bigger problem for someone else to solve later.

I will explain this in more detail below, and I will develop a short list of recommendations that will be summarized at the end.

II. Dispensing Errors - Cause and Prevention

We have analyzed dispensing errors in community and ambulatory pharmacies to determine how systems can be applied to prevent them. We have been engaged for some time in funding independent research to find out how to absolutely minimize dispensing errors. Some of these studies are soon to be published.

The most basic dispensing errors are:

- Prescription filled with wrong drug.
- Prescription filled with wrong strength.
- Wrong prescription label or auxiliary labels omitted.

An insurance company has reported that more than 80% of claims against pharmacists in the community and ambulatory practice settings arise from these basic mistakes. (Source: Baker, Kenneth R., Pharmacists Mutual Claims Study 1989-1997, Speech, National Association of Chain Drug Stores.)

Automated dispensing systems depend on drug product bar codes to prevent errors in both robotic and manual prescription dispensing processes. I will describe these processes below in some detail. Appendix A depicts these processes in actual operation.

1. Most prescriptions are filled using countable tablets and capsules. In robotic dispensing of countable tablets and capsules, they are poured into the robot's dispensing cell and then automatically counted out into prescription vials by the robot as needed.
 - a. When refilling the dispensing cell, the bar code on the drug product (stock bottle) is scanned and matched to the bar code on the cell. A picture of the tablet or capsule is displayed for further verification.
 - b. Prescriptions are then transmitted to the robot and queued for dispensing.
 - c. The robot verifies the bar code on the dispensing cell before it counts out the drug.
 - d. Then the robot counts the tablets or capsules into the vial.
 - e. Next the robot prints and applies the prescription label. The label contains a bar code, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

f. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.

There are more than 2,000 systems of this type in use today. Pharmacists using these systems have claimed that it is almost impossible to dispense the wrong drug or strength, or attach the wrong label.

"I could tell immediately that with the bar code technology, the SP 200 would improve our error rate. The time-saving features of the ScriptPro system are evident as well."

--*Danny Cottrel*

President, Brewton Medical Center Pharmacy, Brewton, AL

With bar code scanning, the SP 200 is virtually foolproof. It is extremely accurate on making sure the patient gets the right drug."

--*Dan Brown*

Director of Pharmacy, San Joaquin General Hospital, French Camp, CA

2. Prescriptions that are not filled using countable tablets and capsules are typically filled using prepackaged items such as inhalers, birth control packs, etc. These are often called "unit-of-use medications" or "patient packs." In robotic dispensing of patient packs, they are presented to the robot and automatically stored. They are then picked by the robot for dispensing as needed.

a. When presenting a patient pack to the robot for storage, the bar code on the drug product (patient pack) is scanned. This identifies the drug to the robot so that it can be stored and tracked automatically.

b. Prescriptions are then transmitted to the robot and queued for dispensing.

c. The robot then picks the patient pack for dispensing.

d. The operator then scans the bar code on the patient pack, again verifying its identification.

e. Next the robot prints the prescription label and presents it to the operator for application to the patient pack. The label contains a bar code identifying the drug, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

f. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.

The robotic systems described above support efficient and accurate dispensing of most prescription drugs. There are also systems that support the manual dispensing

of prescriptions. These systems use the bar code labels on drug products as well to prevent basic dispensing errors.

3. For manual dispensing, the prescriptions are queued on the screen at a prescription filling station. The operator uses the station to manually fill and label the prescriptions.
 - a. The screen display shows the operator which prescriptions are to be filled.
 - b. The operator fills a prescription by picking the required drug product and scanning its bar code at the station. The filling is aborted unless the bar code scan confirms that the correct drug product has been selected.
 - c. The station then prints the prescription label and presents it to the operator for application to the drug product. The label contains a bar code, a picture of the drug, descriptive information regarding the drug and auxiliary labels.
 - d. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.

There are other dispensing errors that can occur:

- Wrong prescription in bag provided to patient.
- Wrong bag provided to patient.
- Failure to provide all prescriptions.
- Failure to provide counseling to patient.

Again, bar codes are used to prevent errors:

1. When filling the bag.
 - a. The station prints a bar code label for the bag that is to be given to the patient. This bar code is unique and associates all prescriptions for the patient with the bag.
 - b. Bar codes on prescription labels are then matched to the bar code on the bag. The bag is not considered complete until all prescriptions for the patient have been scanned and matched.
2. When providing the bag to the patient.
 - a. Patient presents card (or other document) with identifying bar code.
 - b. Scan of patient card prompts display of bag(s) to be provided.

- c. Bag labels are scanned for match to patient.
- d. Patient is prompted to obtain counseling and sign for receipt of prescription via electronic signature device.

These systems prevent errors by controlling and tracking every step in the dispensing process. They record every action, every drug product and every person involved. Bar codes form the electronic chain that holds the system together. The electronic chain runs:

- from the drug product bar code
- to the prescription label bar code
- to the prescription bag bar code
- to the patient bar code
- to the electronic signature of the patient that confirms receipt of the prescription and counseling

Attached to every link in the chain is the bar code of the person responsible for that step. The final link is the patient's own signature. Reports and inquiries are available to track the entire dispensing process.

The first link in the chain is the drug product bar code. Without that link, there can be no complete chain.

III. Bar Code Driven Systems

The systems described above are literally driven by bar codes on drug products. In other words, the routine actions of the personnel and equipment are to a large extent determined by what the bar code scanners read. This design makes the systems easy to use, efficient and foolproof. It also frees up the people involved so they can focus on the critically important, non-routine items like patient care, counseling and medical analysis.

The good news is that some of the most serious problems facing community and ambulatory pharmacies can be addressed simultaneously using the efficiency and accuracy of bar code driven systems:

- There is a critical shortage of pharmacists.
- Dispensing errors occur too often.
- Patient wait time is a source of dissatisfaction.
- Pharmacies often fail to provide adequate patient counseling.

In other words, by improving the use of bar codes on drug products, we can make a significant contribution toward solving a number of serious problems facing our healthcare systems. Virtually everyone involved will benefit.

IV. Bar Codes on Drug Products - Shortcomings

There are shortcomings in the bar codes on drug products and related medical supplies that are prescribed along with them. These shortcomings undermine the efficiency of pharmacy dispensing and present opportunities for errors to occur.

- Some drug products do not have any identifying bar code.
 - Lot number and expiration date information is not in bar code format.
 - Bar codes in use do not always allow positive identification of drug products.
 - There are fundamental flaws in the systems that assign identifying numbers and bar codes to drug products. This results in multiple drug products having the same bar codes and other problems.
1. No identifying bar codes on some drug products.
 - a. A drug product is identified by its National Drug Code (NDC number), which is assigned pursuant to a plan administered by the FDA.
 - b. Most drug stock bottles and packages display the NDC in character form, and also as both character and graphic elements of the Uniform Product Code (UPC number and bar code). The UPC is an industry assigned number used primarily for stockkeeping purposes.
 - c. However, some drugs (and prescribed medical supplies) do not have UPC bar codes on them. These drugs normally display the NDC, which is used to identify and verify the drug manually during the dispensing process. Also, some drugs do not display the NDC at all, and display only the UPC.
 - d. The NDC number is normally the middle part of the UPC number, but there is no industry standard (or consistent practice) that assures that the NDC can be determined from the UPC. Sometimes the NDC and UPC are completely different numbers.
 - e. This means that guesswork is sometimes required to identify a dispensed drug product. This not only wastes time, but it also opens the door for errors.
 - f. We recommend that the NDC be displayed clearly on all pharmaceutical products and prescribed medical supplies, and that the NDC also be included and displayed on these products in bar code form in a standard way (such as in a standard position within the UPC). This will allow all drug stock bottles and packages to be positively identified via their UPC bar code.

2. No lot number and expiration date bar codes on drug products.

a. Drug stock bottles and packages typically display a lot number and expiration date, but not in bar code form. Those that do, typically display this information in a separate bar code. Dispensing pharmacies must track lot numbers and expiration dates to ensure that drugs are not used beyond expiration dates, deal with recalls, etc. This information is typically entered manually, and sometimes omitted or entered incorrectly.

b. A simple calculation shows that pharmacists and technicians can waste tremendous amounts of time manually entering and tracking lot numbers and expiration dates. There are approximately three billion prescriptions filled annually in community and ambulatory pharmacies. Assuming a conservative time figure of 15 seconds to enter lot number and expiration date information for each prescription, 12.5 million hours per year are spent on this task alone. This accounts for more than 6,000 Full-Time Employees (FTEs).

c. Prescription volumes are expected to increase by 40% over the next 3-5 years. In other words, in addition to an estimated 6,000 FTE's currently spent on this task, approximately 2,400 additional FTE's will be wasted over the next 3-5 years simply entering lot numbers and expiration dates while dispensing drugs.

d. The shortage of pharmacists has reached a critical level and all projections show that the crisis is in a very early stage with no relief in sight. We are now hearing reports of pharmacy technician shortages.

e. A comparison with pharmacy school projections shows that continued manual entry of lot numbers and expiration dates has the potential to waste 25% or more of the supply of new pharmacists graduating each year.

f. We recommend that all drug products and prescribed medical supplies include, within the identifying bar code (such as within the UPC), the lot number and expiration date so that a single scan of the product can obtain the identity of the product, its lot number and its expiration date. This will allow pharmacy dispensing systems to automatically obtain and utilize lot number and expiration date information without manual entry.

3. Bar codes in use do not allow positive identification of drug products.

a. Manufacturers sometimes make changes in the manufacturing process that modify the physical appearance of a drug without changing it from a therapeutic standpoint. This is sometimes done without assigning a different NDC. For example, the drug might have initially been green. One day the drug is changed to white. However, the manufacturer does not change the NDC since it is

considered to be "the same drug." We call this the "multi-version drug" problem. See Appendix B for examples of the multi-version drug problem. Appendix B shows one case where a manufacturer has produced four versions of the drug, all labeled with the same NDC number.

b. Distributors often obtain drugs from manufacturers and repackage or relabel them to sell under their own name. Sometimes these packages are assigned a new NDC and sometimes they are not. Sometimes the packages display two NDC numbers, the original number from the manufacturer and a new number assigned by the distributor. (See Appendix C for example.)

c. Many drugs come in an outer package (such as a box) with multiple interior packages. The outer package can be dispensed, or it can be opened and the interior packages dispensed separately. Sometimes there is no NDC on the outer package. Sometimes there is no NDC on the interior packages. Sometimes the same NDC is shown on both the outer and interior packages. (See Appendix D for example.)

d. The above situations greatly complicate the dispensing process. They also undermine the ability of dispensing personnel and patients to use visual inspection aids to verify dispensing accuracy.

e. We recommend that a separate NDC (and a separate, single identifying bar code) be used when the appearance of the drug or drug package changes, and that each package that can be dispensed be assigned a unique NDC.

f. Positive identification is important not only for pharmacists, but also for patients. The state of Oregon has implemented regulations requiring prescription labels to display descriptive information to allow patients to positively identify the drugs they are taking. In order to do this, computer systems must be able to determine from the NDC of the drug being dispensed which picture and descriptive information to print on the label. Given the present state of affairs, there are cases where neither the dispensing pharmacist nor the patient can be sure what the drug will look like until the package is actually opened.

4. There is confusion, duplication and errors in the NDC identification numbers and UPC bar codes displayed on drug products.

a. "Labelers" of drug products (i.e. manufacturers, and those that repackage or relabel products) typically display both the NDC and the UPC on their product labels.

b. The UPC is displayed in bar code format with the actual number printed below.

c. For drug products, the middle 10 digits of the UPC is typically identical to the NDC, with the first digit of the 12-digit UPC set to "3" and the last digit set as a check digit. However, this is not always the case. Sometimes there is no numerical resemblance between these numbers. (See Appendix E for example.)

d. We recommend that the identifying bar code contain the NDC number in a standard position so that the drug NDC can be positively and directly identified via bar code scan.

5. The NDC numbering system is itself flawed, misused and confusing.

a. The NDC numbering system is based on three separate numbers: Labeler Code, Product ID and Pack Size. However, there is not a coordinated plan as to the exact number of digits in those three numbers.

b. As it has turned out, the Labeler Code can be either four or five digits; the Product ID can be either three or four digits; and the Pack Size can be either one or two digits.

c. However, drug manufacturers, repackagers and labelers, for stockkeeping purposes, need a single number—not three—to identify their drugs. Also, they need the number to be 10 digits so that it fits within the 12-digit UPC number scheme (allowing for a standard leading digit and a trailing check digit). Thus, on drug stock bottles and packages one typically finds the "NDC Number" as a 10-digit concatenation of the three numbers established as the NDC. Sometimes dashes are entered separating these numbers, sometimes not.

d. In other words, the NDC Number is:

The FDA assigned Labeler Code, which may be either four or five digits.

+

The Manufacturer (or Labeler) assigned Product ID, which may be either three or four digits.

+

The Manufacturer (or Labeler) assigned Pack Size (package identifier), which may be either one or two digits.

e. In order for the manufacturers to keep the NDC number to 10 digits, they require that one of the three component numbers be of the "small" size while the other two must be of the "large" size.

f. This plan produced NDC numbers that did not duplicate for a given manufacturer, repackager or relabeler, since the first of the three numbers was assigned uniquely to each of them. However, it did not produce NDC numbers

that were unique across the industry as a whole. For example, the concatenation of 0001+1000+01 yields the 10-digit number 0001100001. Likewise, the concatenation of 00011+000+01 yields the same 10-digit number.

g. Pharmacy database providers could not work directly with this numbering system. They could not tolerate duplicate NDC numbers in their databases. Their solution was to convert the 10-digit NDC numbers to 11 digit numbers by adding a zero in front of whichever of the three fields came in the "small" size. Thus, the "NDC" numbers found in most drug databases and displayed on the computer screens and prescription labels used by pharmacists every day are 11 digits. These numbers are derived from the NDC numbers used by the manufacturers by adding a zero either at the front, in the middle, or near the end.

Unfortunately, duplications sometimes occur when converting 11-digit NDC numbers back to 10-digit NDC numbers. This allows drug products to mis-identified. (See Appendix F.)

h. Given this situation of padding the NDC with a zero (somewhere), it is not trivial to determine from a drug database NDC what the manufacturer NDC is. The procedure is as follows:

- i. First, determine who the Labeler is and look up the Labeler code. This will be either four or five digits.
- ii. If the labeler code is four digits, remove the leading zero from the "NDC" number in the database and you have the manufacturer NDC number.
- iii. If the labeler code is five digits, check other reference materials to determine whether the Product ID or the Pack Size has been specified in the "small" size to determine where to add the leading zero.

Appendix G shows examples of the difficulties of translating UPC bar codes to NDC numbers.

- i. Some manufacturers have used the "Pack Size" field (i.e. the third element of the NDC) to indicate a property of the product rather than the packaging quantity of the product. Normally, Pack Size is used to distinguish the various package sizes that are available. However, as shown in Appendix H, this field has also been used to designate the length of the needles for various syringes.
- j. Sometimes the same bar code references multiple drug products. (See Appendix I for example.)

k. Various types of bar codes are found on drug products and related medical supplies. (See Appendix J for examples.)

l. Appendix K shows an example where three entries in the National Drug Data File (NDDF, supplied by FirstDataBank, Inc.) appear, from their NDC numbers, to be three different package sizes for the same drug. However, the third entry is actually a completely different drug. The source of this misleading data is apparently an error in the expansion of a 10-digit NDC to an 11-digit NDC (described above). Most pharmacy computer applications use the NDDF to perform Drug Utilization Reviews and adjudicate prescription claims. The NDDF is also used by payors to pay prescription claims.

m. Problems such as these are encountered the very first hour of the very first day on the job by anyone who works in a pharmacy. Unfortunately, encountering the problems does not mean that they are understood or solved. As can be seen from the above, translating from database NDC numbers to manufacturer NDC numbers and interpreting the NDC numbers is cumbersome. It wastes time and confuses people.

These problems cause stress and errors. They are classic "Murphy's Law" examples of how lack of coordination and clarity in establishing standards can produce an incredible, large scale mess. We should clean up this mess before multiplying it by bringing in an even wider range of products. How can we expect those who work in pharmacies to keep up with staggering workloads and avoid dispensing the wrong drugs when they need a road map to identify the very products that the industry provides for them to dispense?

V. Far Reaching Problems

We can testify that the problems described above are far reaching.

1. We develop and maintain systems used in pharmacy dispensing, and we do everything possible to make these systems function efficiently and error-free. This is a very challenging task, given the range of problems and exceptions described above.

2. We develop and maintain drug databases used by these systems. The databases must cope with whatever drug products the pharmaceutical industry turns out and then make sense of how they are labeled. For example, much time is spent dealing with the ongoing problem of multi-version drugs, where drugs change in appearance without new NDC numbers assigned. Also, numerous cross-reference tables must be maintained in order to deal with all of the identification numbers and bar codes found on drug products.

3. We train pharmacists and pharmacy technicians to use these systems. We see the frustration and confusion that these problems cause. Often, the best we can do for the people on the front line is to interrupt robotic processing and let them know that there is an exception that they need to resolve manually.
4. We provide continuous help desk and on-site support and training for the users of these systems. We know firsthand that errors do occur because of these problems.

We believe that the most important steps government can take to help the pharmacy industry cope with the burgeoning workload and avoid dispensing errors is to clean up the identification system for drug products and implement bar code standards.

VI. Recommendations

- A. The system for numbering drug products should be fixed, so that the FDA, manufacturers, repackagers, database developers, pharmacists, patients and other interested parties can all reference a drug using the same NDC number in a standard format.
- B. The NDC number should be displayed in a standard format on stock bottles and packages for all dispensed drug products and prescribed medical supplies. It should also be displayed on these products in bar code form in a standard format, possibly within an enhanced UPC bar code.
- C. The lot number and expiration date should be displayed on stock bottles and packages for all dispensed drug products and prescribed medical supplies. This information should also be included in bar code form, within the bar code containing the NDC number, in a standard format, possibly within an enhanced UPC bar code.
- D. A new NDC (and bar code) should be assigned when the physical appearance of the drug or its package changes.
- E. A separate NDC number (and bar code) should be assigned to each drug package that can be dispensed.
- F. There should be only one bar code on a drug product or prescribed medical supply item. If the existing UPC bar code cannot be adapted to meet the needs of these products, a single unifying bar code standard should be adopted.

From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
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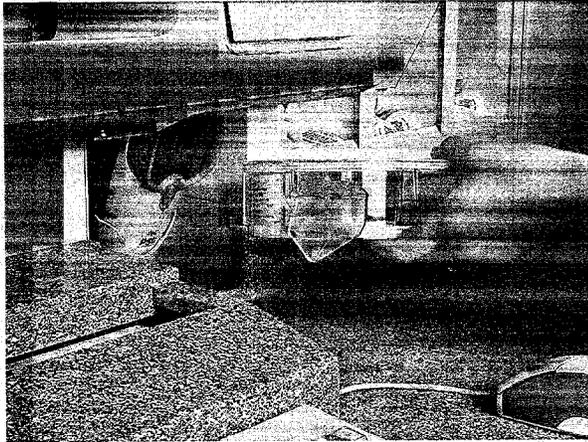
APPENDIX A - PRESCRIPTION DISPENSING PROCESS

1. Most prescriptions are filled using countable tablets and capsules. In robotic dispensing of countable tablets and capsules, they are poured into the robot's dispensing cell and then automatically counted out into prescription vials by the robot as needed.

a. When refilling the dispensing cell, the bar code on the drug product (stock bottle) is scanned and matched to the bar code on the cell. A picture of the tablet or capsule is displayed for further verification.



Scanning Stock Bottle, SP 200



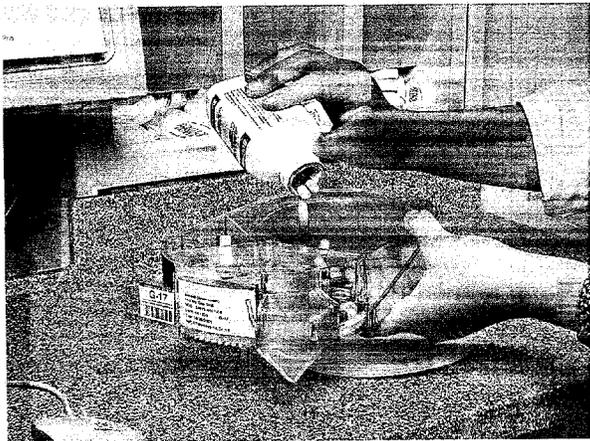
Scanning Cell, SP 200

Cell Data			
Scanned Cell ID	E1-43	Expected Cell ID	E1-43
Expected NDC	08378035100	Drug Data	
Cell Size	Single-height	Owner	krone?
Scanned NDC		Quantity Added	0
Cell Type		Current Quantity	57
Flowgate Type	0	Flowgate Code	
Flowgate Setting		Default	
Platform Type	0	Previous Quantity	100
Hub Type	Smooth	Drug Lot #	1011111
Drug Name	Haloperidol 0.5 mg Tab Mylan	Lot Exp.	07/01/2003
Label Image	08378035100	00378	
<input type="button" value="Show Cell Actions"/>			
<input type="button" value="Print New Cell Label"/> <input type="button" value="OK"/>			
<input type="button" value="Cancel"/>			
<input type="button" value="Remove From Cell"/>			
Haloperidol 0.5 mg Tab Mylan Round Lt. Peach Solid Single-scored MYLAN 351 Dispensed 1 scripts since last reset. Script count last reset at: 07/01/2002 12:56:53 <input type="button" value="Reset Script Counter"/>			
Dispensed 60 units since last reset. Unit count last reset at: 07/01/2002 12:56:53 <input type="button" value="Reset Unit Counter"/>			

Pill Drug Information, SP 200

Cell Data			
Scanned Cell ID	E1-43	Expected Cell ID	E1-43
Expected NDC	08378035100	Drug Data	
Cell Size	Single-height	Owner	krone?
Scanned NDC		Quantity Added	0
Cell Type		Current Quantity	57
Flowgate Type	0	Flowgate Code	
Flowgate Setting		Default	
Platform Type	0	Previous Quantity	100
Hub Type	Smooth	Drug Lot #	1011111
Drug Name	Haloperidol 0.5 mg Tab Mylan	Lot Exp.	07/01/2003
Label Image	08378035100	00378	
<input type="button" value="Show Cell Actions"/>			
<input type="button" value="Print New Cell Label"/> <input type="button" value="OK"/>			
<input type="button" value="Cancel"/>			
<input type="button" value="Remove From Cell"/>			
Haloperidol 0.5 mg Tab Mylan Round Lt. Peach Solid Single-scored MYLAN 351 Dispensed 1 scripts since last reset. Script count last reset at: 07/01/2002 12:56:53 <input type="button" value="Reset Script Counter"/>			
Dispensed 60 units since last reset. Unit count last reset at: 07/01/2002 12:56:53 <input type="button" value="Reset Unit Counter"/>			

Stock Drug Information, SP 200



Pouring Pills into Cell, SP 200

b. Prescriptions are then transmitted to the robot and queued for dispensing.

SP 200 User Interface

File SP System View Configure Help

Filled Scripts				System Messages	
Script #	Patient Name	Drug Name	Quan...	Synopsis	Time
? 0000458874	Lori Peacock	Amoxicillin 500 mg Cap Teva	4	Cell Empty H-13	02/17/1999 10:27:32
? 0000458872	Max Skidmore	Hydrocod/APAP 5/500 mg Tab MKC	20	Emergency Stop Off	02/17/1999 09:40:49
? 0000458855	Sherri Parker R	Ciaritin (Loratadine) 10 mg Tab Scher...	30	Main Door Closed	02/17/1999 09:40:46
				Emergency Stop	02/17/1999 09:35:54
				Main Door Open	02/17/1999 09:35:50
				Label Ribbon Low	02/17/1999 09:15:09
				Labeler Door Closed	02/17/1999 09:13:08
				System Error	02/17/1999 08:51:52

Pending Scripts							
Script #	Patient Name	Drug Name	Priority	Priority Gr.	Quantity	ETA	Excep. Com.
0000458854	Sherri Parker R	Amoxicillin 250mg Cap Biocraft	9	Tomorrow	42	10:31	
0000458854	Sherri Parker R	Amoxicillin 250mg Cap Biocraft	9	Tomorrow	42	10:31	
0000458887	Cindy Carter	Amoxicillin 500 mg Cap Teva	9	Tomorrow	30	10:32	
0000458890	RONC SR. HAINES	Ibuprofen 800 mg Tab Greenstone	9	Tomorrow	30	10:32	
0000458879	James Hazelhurst	Hydrocod/APAP 5/500 mg Tab MKC	9	Tomorrow	40	10:33	
0000458875	James Hazelhurst	Amoxicillin 500 mg Cap Teva	9	Tomorrow	30	10:33	

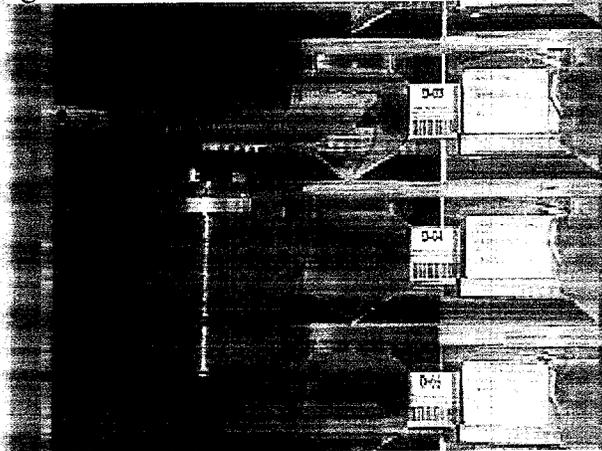
Drugs Assigned To Cells Priority Groups Verified Scripts Cancelled Scripts Rejected Scripts					
Cell	Drug Name	Quantity	Low Quant	Expiration Date	
B-03	Amoxil (Amoxicillin) 250 mg Cap SKB	500	200	01/14/2000	
B-20	Aspirin 325 mg ECTab Major	1993	200	01/15/2000	
E-11	Aspirin 325 mg ECTab Rugby	904	200	01/14/2000	
A-18	Atenolol 100 mg Tab Lederle	1000	50	01/15/2000	
G-21	Atenolol 50 mg Tab Lederle	1000	50	01/14/2000	

For Help, press F1

[CAP NUM]

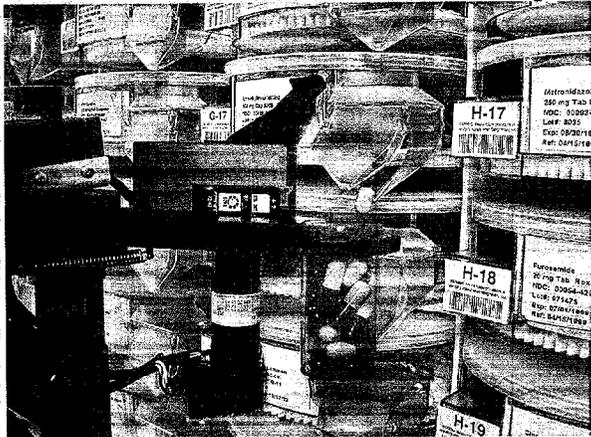
Pending Script Queue, SP 200

c. The robot verifies the bar code on the dispensing cell before it counts out the drug.



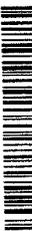
Robot Scanning Cell Before Dispensing, SP 200

d. Then the robot counts the tablets or capsules into the vial.

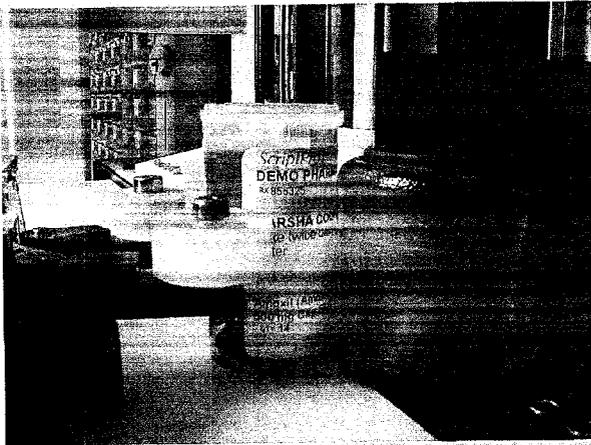


Counting Pills Into Vial, SP 200

e. Next the robot prints and applies the prescription label. The label contains a bar code, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

ScriptPro 5828 Reeds Road Mission, KS 66202 USA RX 123463 DR D. J. DOW JANE D PUBLIC TAKE ONE TABLET BY MOUTH DAILY.	www.scriptpro.com (913) 384-1008 10/03/2001		 Take with food.  Avoid grapefruit or grapefruit juice.
Premarin (Conj. Estrogens) 0.9 mg Tab WAY Exp. Date: 10/03/2002 QTY 30	Lot# 1234 RPh: NRW REF 10 Time(s)		Oval, Pink Premarin
<small>CAUTION: Federal law prohibits dispensing without prescription. Drug to stay precise. Give your patient the return prescription.</small>			

Label, SP 200



Label Being Applied, SP 200

f. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.



Operator Scanning Vial, SP 200



Verification Display, SP 200

There are more than 2,000 systems of this type in use today. Pharmacists using these systems have claimed that it is almost impossible to dispense the wrong drug or strength, or attach the wrong label.

"I could tell immediately that with the bar code technology, the SP 200 would improve our error rate. The time-saving features of the ScriptPro system are evident as well."

--*Danny Cottrel*

President, Brewton Medical Center Pharmacy, Brewton, AL

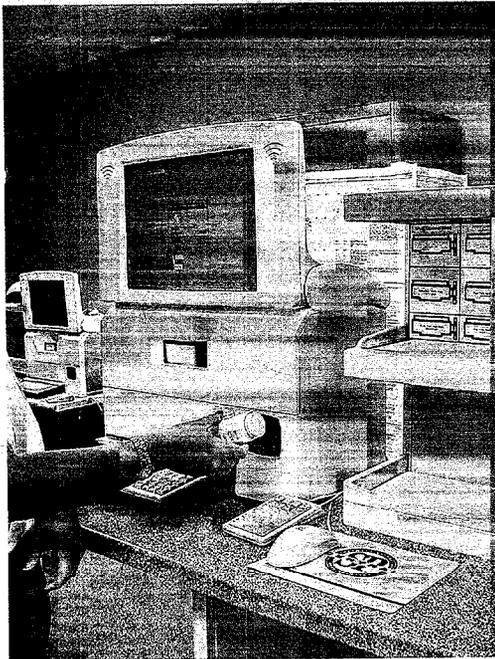
With bar code scanning, the SP 200 is virtually foolproof. It is extremely accurate on making sure the patient gets the right drug."

--*Dan Brown*

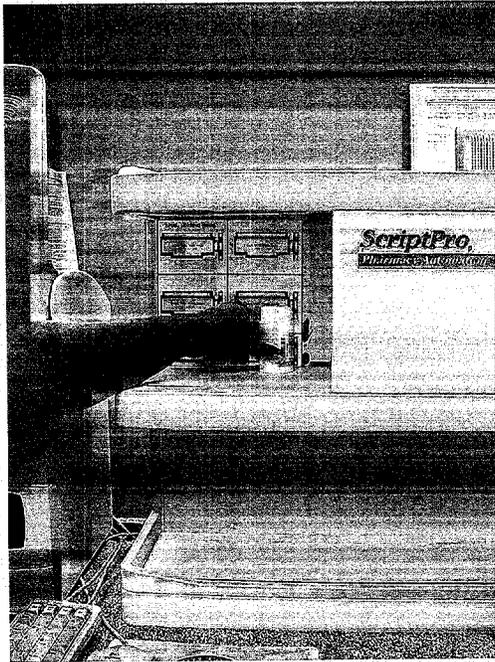
Director of Pharmacy, San Joaquin General Hospital, French Camp, CA

2. Prescriptions that are not filled using countable tablets and capsules are typically filled using prepackaged items such as inhalers, birth control packs, etc. These are often called "unit-of-use medications" or "patient packs." In robotic dispensing of patient packs, they are presented to the robot and automatically stored. They are then picked by the robot for dispensing as needed.

a. When presenting a patient pack to the robot for storage, the bar code on the drug product (patient pack) is scanned. This identifies the drug to the robot so that it can be stored and tracked automatically.



Scanning Patient Pack for Input, SPUD



Placing Patient Pack on Conveyor, SPUD

b. Prescriptions are then transmitted to the robot and queued for dispensing.

ScriptPro - SP Central User Interface (Full Family Profile) [SPUD - L-UI-10000005-01]

File Edit Configure Launch Help

Dispense & Store Connected

SPUD Pending

Script #	Patient Name	Drug Name	Qty	Priority	Status	Requested
983111	Test, Jane	Escoproped Prednisolone 0.15% Ophth Susp Alc	1	BUSH	SPUD In Pro...	05/08/2003

1 Records

SPUD Filled

Script #	Patient Name	Drug Name	Qty	Priority	Status	Requested
----------	--------------	-----------	-----	----------	--------	-----------

0 Records

Conveyor #	Drug Name	Qty	Troy Qty	Rejoid Qty	Exp Date	Reorder Cnda
N-19	Accolate Zafirlukast 20 mg Tab AstraZen	60	60	4	04/05/2003	251-4990
N-19	Accolate Zafirlukast 20 mg Tab AstraZen	60	60	4	04/05/2003	251-4990
N-19	Accolate Zafirlukast 20 mg Tab AstraZen	60	60	4	04/05/2003	251-4990
N-19	Accolate Zafirlukast 20 mg Tab AstraZen	60	60	4	04/05/2003	251-4990
N-02	Accolate Zafirlukast 20 mg Tab AstraZen	60	60	4	04/05/2003	251-4990
N-02	Accolate Zafirlukast 20 mg Tab AstraZen	60	60	4	05/08/2003	251-4990

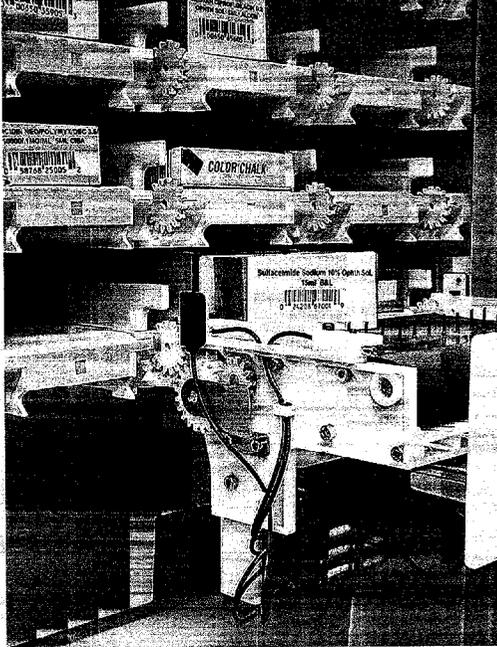
Drugs Assigned to SPUD

Script View Machine View

SP 200 SPUD Script Fill Script Fill/Verify Processing Exceptions Will Call Manager Partial Fill Data Storage Hardware Status

Pending Script Queue, SPUD

c. The robot then picks the patient pack for dispensing.



Patient Pack Being Picked from Conveyor, SPUD



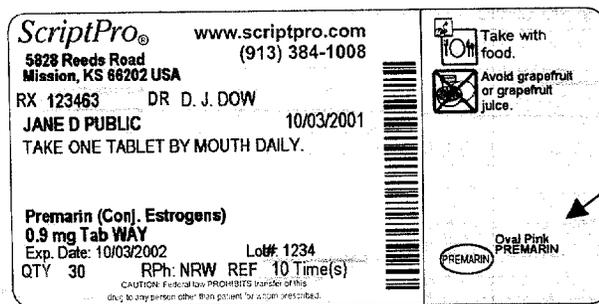
Patient Pack on Outfeed Conveyor, SPUD

d. The operator then scans the bar code on the patient pack, again verifying its identification.



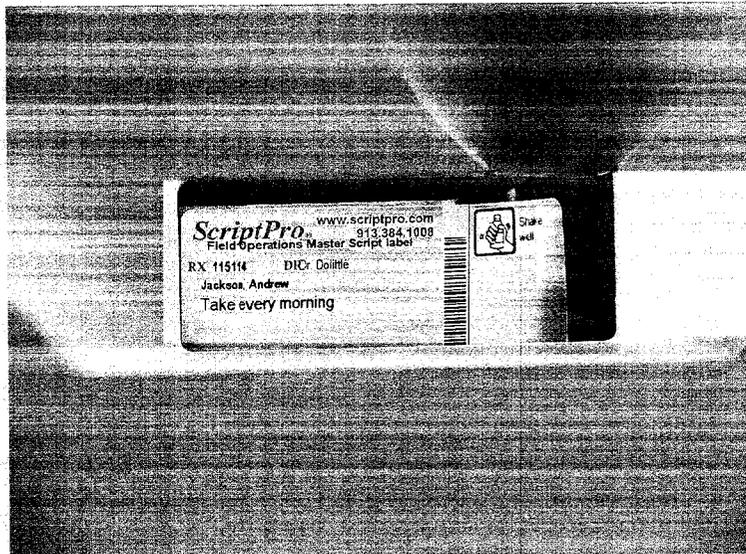
Patient Pack Being Scanned for Labeling, SPUD

e. Next the robot prints the prescription label and presents it to the operator for application to the patient pack. The label contains a bar code identifying the drug, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

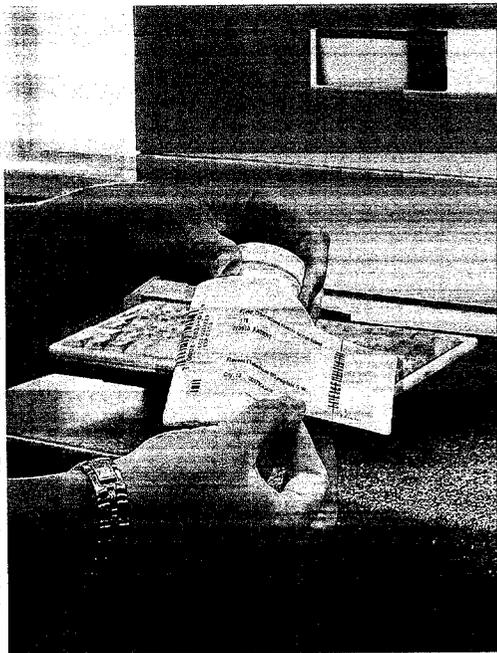


Oval, Pink
Premarin

Label, SPUD



Label Presented for Peeling, SPUD



Label Being Applied, SPUD

f. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.



Operator Scanning Label & Verification Display, SPUD

The robotic systems described above support efficient and accurate dispensing of most prescription drugs. There are also systems that support the manual dispensing of prescriptions. These systems use the bar code labels on drug products as well to prevent basic dispensing errors.

3. For manual dispensing, the prescriptions are queued on the screen at a prescription filling station. The operator uses the station to manually fill and label the prescriptions.

a. The screen display shows the operator which prescriptions are to be filled.

ScriptPro SP Central User Interface (D:\WEBSTER_NO_SP200_TAB\app\STATION1\SPUD0089-01)

File Edit Configure Launch Help

Disconnected

Fill/Verify/Batch

Pending Work List

Script #	Patient Name	Drug Name	Qty	Priority	Status	Requested
334466	Reginald, DeSouza	Humalog Insulin Lispro 100 un/mL Inj Lilly	1	RUSH	Pending	04/26/2002
123466	Davis, Joan	Nasonex Mometasone 50 mcg Nas Spray Scheri...	2	RUSH	Pending	04/26/2002
123658	Davis, Joan	Aller-chlor Chlorpheniramine 2 mg/5 mL Syrup R...	1	RUSH	Pending	04/26/2002
123657	Johnson, Daniel	Ibuprofen (Berry) Ibuprofen 100 mg/5 mL Susp C...	1	RUSH	Pending	04/26/2002
123541	Johnson, Daniel	Animal Shapec Multivitamin Chewtab Major	100	RUSH	Pending	04/26/2002
123587	Adams, James	Aspirin w/Codaine #3 ASA/Codaine 325/30 mg ...	25	RUSH	Pending	04/26/2002

6 Records

Fill Workspace

Script #	Patient Name	Drug Name	Qty	Priority	Status	Requested

0 Records

Verify Workspace

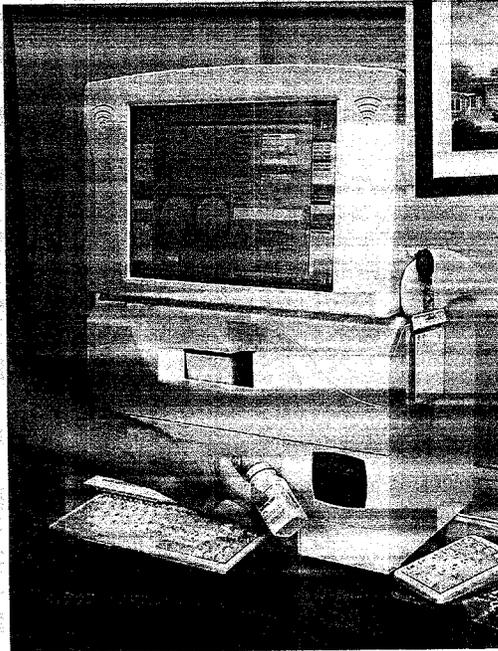
Script #	Patient Name	Drug Name	Qty	Priority	Status	Requested

0 Records

Fill Fill/Verify/Batch Fill/Verify/Dispense Processing Exceptions Wait Call Manager Partial Fill/Out of Stock Data Storage

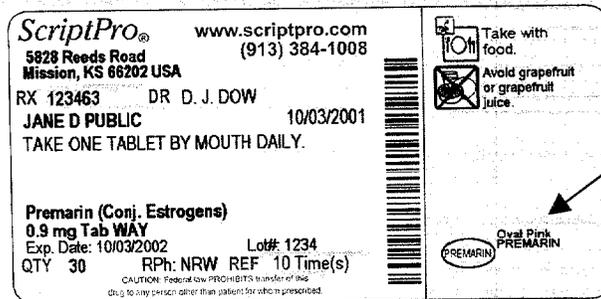
Pending Script Queue, SP Station

b. The operator fills a prescription by picking the required drug product and scanning its bar code at the station. The filling is aborted unless the bar code scan confirms that the correct drug product has been selected.



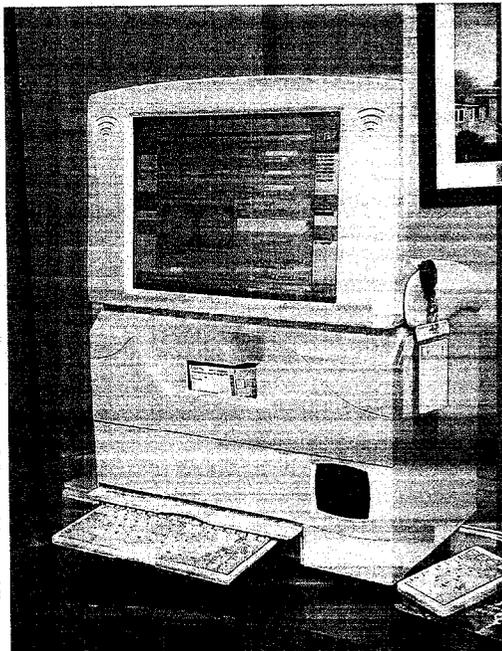
Drug Product Being Scanned for Labeling, SP Station

c. The station then prints the prescription label and presents it to the operator for application to the drug product. The label contains a bar code, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

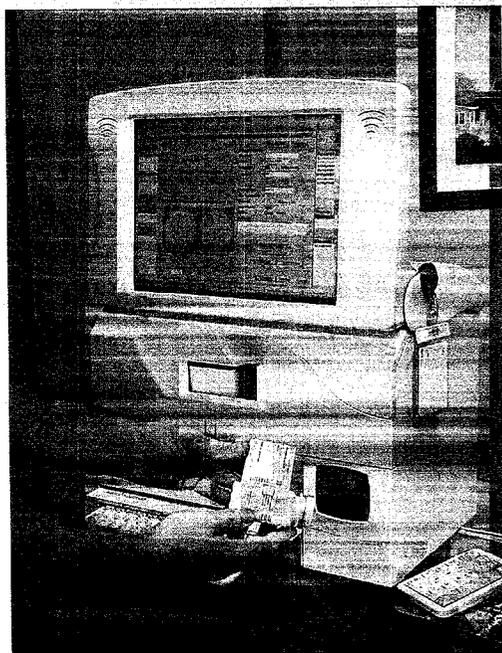


Oval, Pink
Premarin

Label, SP Station

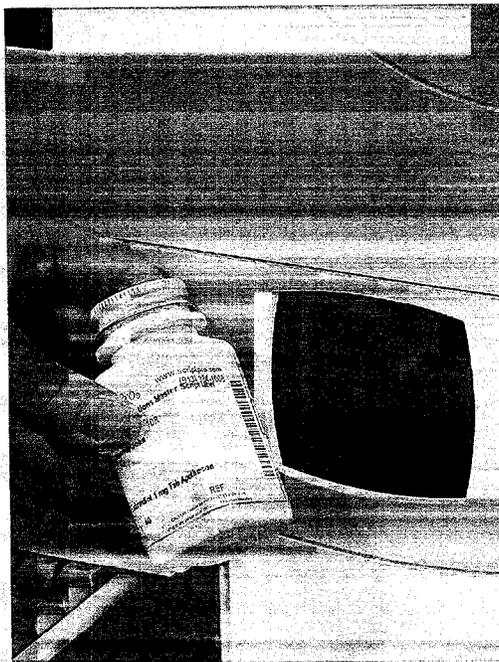


Label Presented for Peeling, SP Station

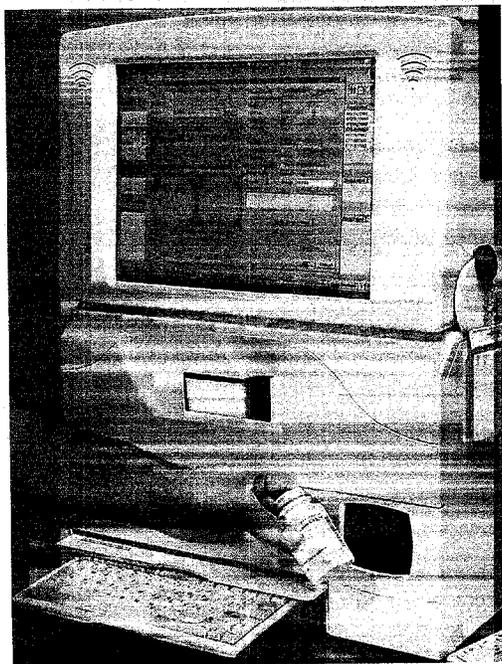


Label Being Applied, SP Station

d. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.



Operator Scanning Label, SP Station



Verification Display, SP Station

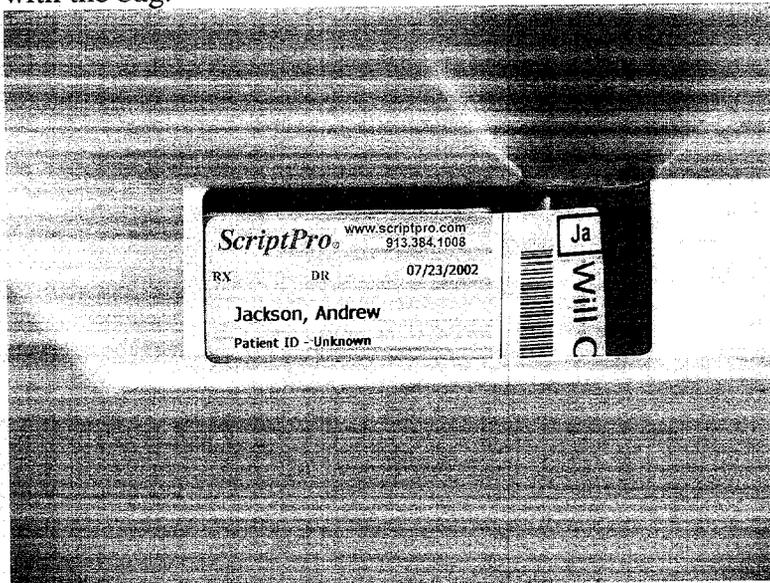
There are other dispensing errors that can occur:

- Wrong prescription in bag provided to patient.
- Wrong bag provided to patient.
- Failure to provide all prescriptions.
- Failure to provide counseling to patient.

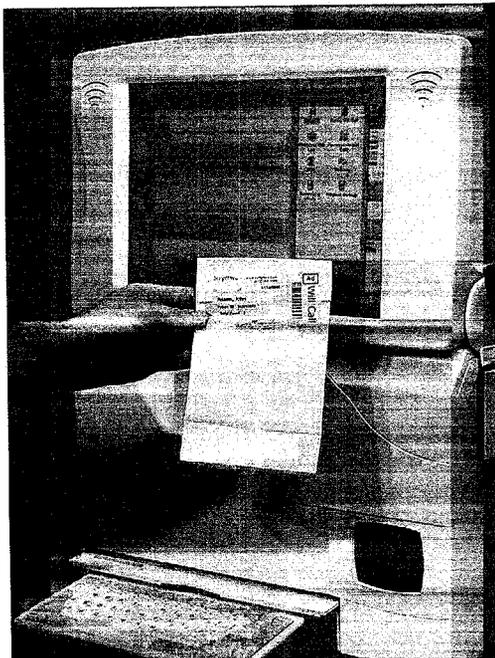
Again, bar codes are used to prevent errors:

1. When filling the bag.

- a. The station prints a bar code label for the bag that is to be given to the patient. This bar code is unique and associates all prescriptions for the patient with the bag.

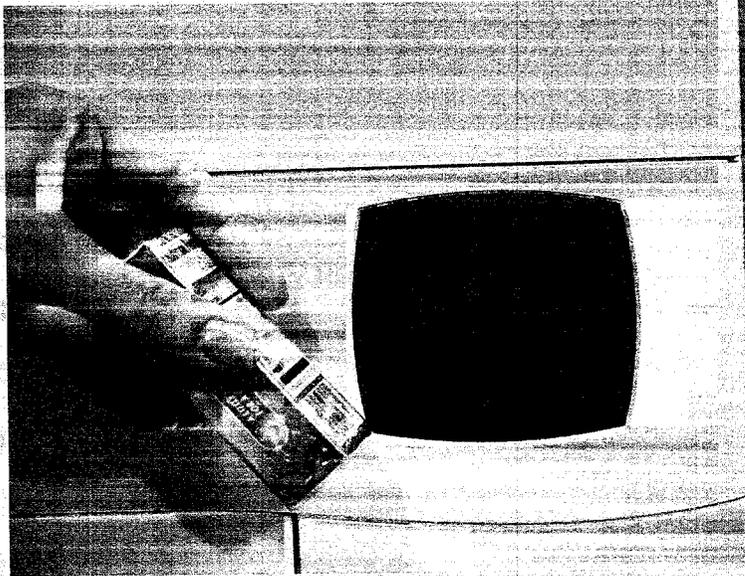


Bag Bar Code Label Printed, SP Station

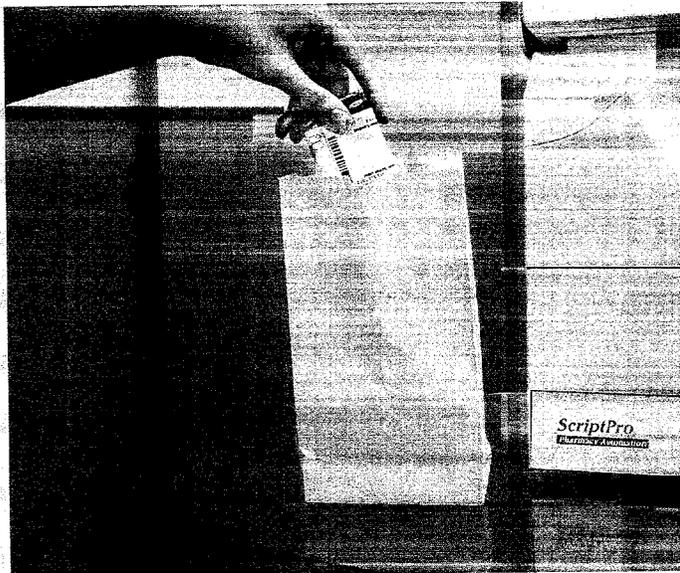


Bag Bar Code Label Applied to Bag, SP Station

b. Bar codes on prescription labels are then matched to the bar code on the bag. The bag is not considered complete until all prescriptions for the patient have been scanned and matched.



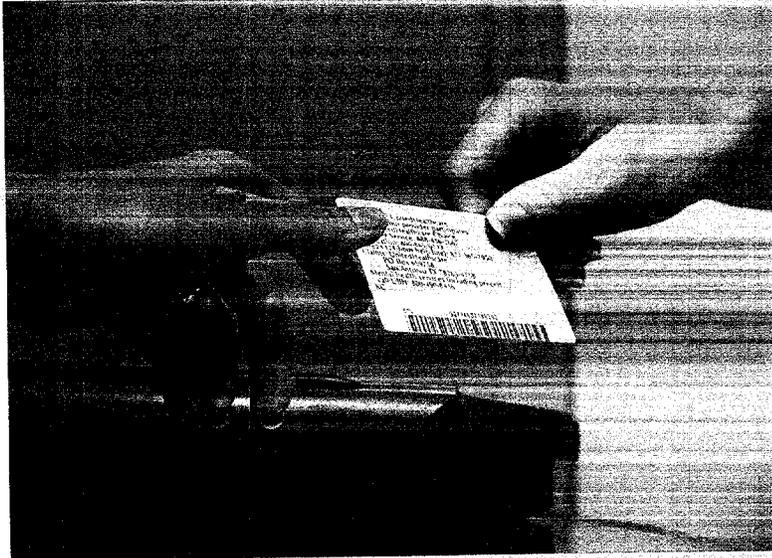
Prescription Bar Code Scanned, SP Station



Prescriptions Into Bag, SP Station

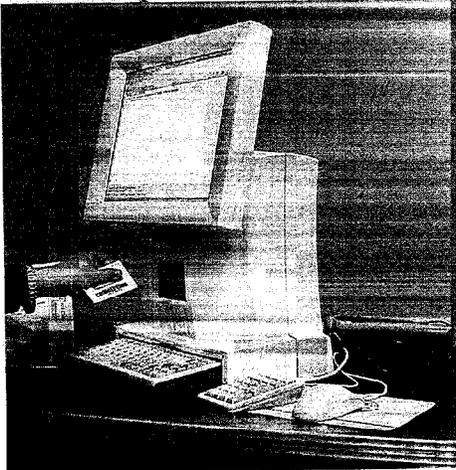
2. When providing the bag to the patient.

a. Patient presents card (or other document) with identifying bar code.

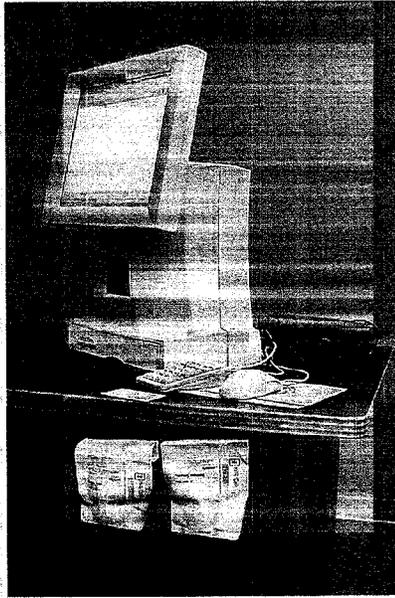


Patient Presents Card

b. Scan of patient card prompts display of bag(s) to be provided.

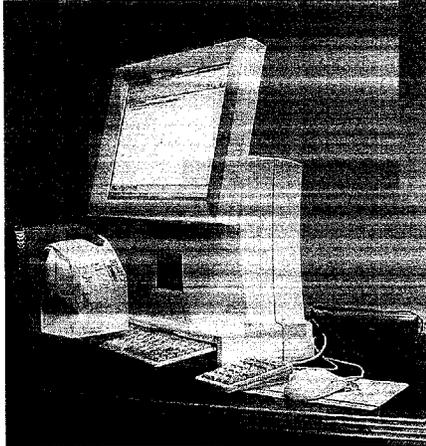


Patient Card Scanned, SP Checkpoint



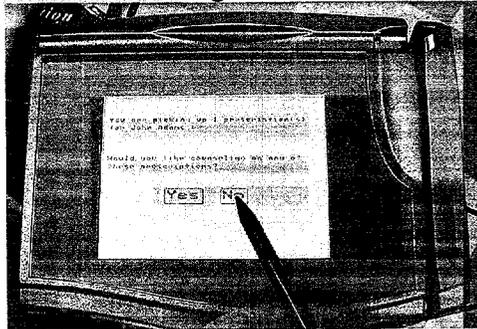
Display of Bags for Patient, SP Checkpoint

c. Bag labels are scanned for match to patient.

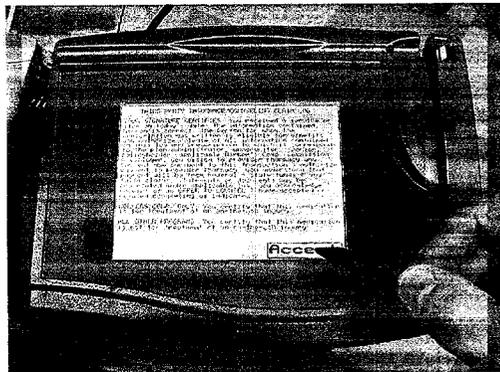


Bag Bar Code Scanned, SP Checkpoint

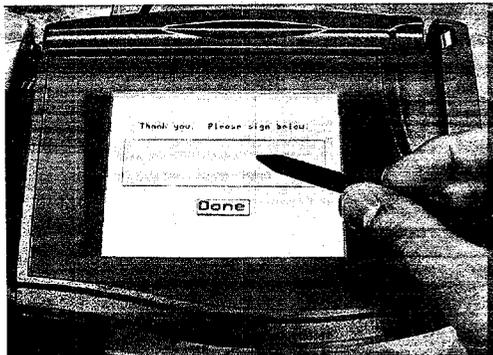
d. Patient is prompted to obtain counseling and sign for receipt of prescription via electronic signature device.



Patient Prompted for Counseling, Electronic Signature Device



Patient Counseling Information, Electronic Signature Device



Patient Signature, Electronic Signature Device

From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
Bar Code Label Requirements for Human Drug Products
July 26, 2002, from 9 a.m. to 5 p.m.
Natcher Auditorium, Building 45
National Institutes of Health, Bethesda, MD

**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
BIOLOGIC PRODUCTS**

APPENDIX B - MULTI-VERSION DRUG PROBLEM

The screenshot shows a 'Drug Data' window with the following fields and values:

- Drug Name: Aspirin 325 mg EC Tab Rugby
- Drug Packages: Default | Label | 01 | 10
- Drug NDC: 00536-3313-00
- Pharmacy Drug ID: [Empty]
- Brand Name: [Empty]
- Generic Name: Aspirin
- Strength / Unit: 325 mg
- Dosage Form: EC Tab
- Distributor: Rugby
- Shape: Round
- Color Pattern: Solid
- Color: Bright Orange
- Scoring: No Scoring
- Markings: 11106
- Units Per 12: 67
- Dram: [Empty]
- Storage Loc.: <none selected>
- Product type: Rx-NDC
- DEA Schedule: [Empty]

Additional features and options:

- Checkmark: Use Front Image Only on Label
- Description: Swallow tablet(s) whole. Take with a full glass of water.
- Require Package Code Match on Fill:
- Subscribed:
- Drug Version #: 1
- Quantity Verification options:
 - No recount required
 - Recount / Dispose of excess
 - Recount / Return excess to fill device
 - Recount / Return excess to stock
 - Warn if overcount detected

Drug Data [X]

Main | SP 200/SP 100

Drug Name: Aspirin 325 mg EC Tab Rugby Drug Packages

Drug NDC	00536-3313-00	Default	Label	01	10
Pharmacy		Multiple Images Available			
Drug ID		Multiple Images Available			
Brand Name					
Generic Name	Aspirin				
Strength / Unit	325 mg				
Dosage Form	EC Tab				
Distributor	Rugby				
Shape	Round				
Color Pattern	Solid				
Color	Bright Orange				
Scoring	No Scoring				
Markings	T				
Units Per 12 Dram	73				
Storage Loc.	<none selected>				
Product Type	Rx-NDC	DEA Schedule			

Use Front Image Only on Label

Description Swallow tablet(s) whole. Take with a full glass of water.	<input type="checkbox"/> Require Package Code Match on Fill	Quantity Verification <input checked="" type="radio"/> No recount required <input type="radio"/> Recount / Dispose of excess <input type="radio"/> Recount / Return excess to fill device <input type="radio"/> Recount / Return excess to stock <input type="radio"/> Warn if overcount detected	Add	Delete
	<input checked="" type="checkbox"/> Subscribed			
	Drug Version #			
	2			

Add Delete ← → ↻

OK Cancel Apply

Drug Data [X]

Main | SP 200/SP 100

Drug Name: Aspirin 325 mg EC Tab Rugby Drug Packages

Drug NDC	00536-3313-00	Default	Label	01	10
Pharmacy		Multiple Images Available			
Drug ID		Multiple Images Available			
Brand Name					
Generic Name	Aspirin				
Strength / Unit	325 mg				
Dosage Form	EC Tab				
Distributor	Rugby				
Shape	Round				
Color Pattern	Solid				
Color	Bright Orange				
Scoring	No Scoring				
Markings	44 227				
Units Per 12 Dram	65				
Storage Loc.	<none selected>				
Product Type	Rx-NDC	DEA Schedule			

Use Front Image Only on Label

Description Swallow tablet(s) whole. Take with a full glass of water.	<input type="checkbox"/> Require Package Code Match on Fill	Quantity Verification <input checked="" type="radio"/> No recount required <input type="radio"/> Recount / Dispose of excess <input type="radio"/> Recount / Return excess to fill device <input type="radio"/> Recount / Return excess to stock <input type="radio"/> Warn if overcount detected	Add	Delete
	<input checked="" type="checkbox"/> Subscribed			
	Drug Version #			
	3			

Add Delete ← → ↻

OK Cancel Apply

Main		SP 200/SP 100	
Drug Name		Aspirin 325 mg EC Tab Rugby	
Drug Packages		Default Label 01 10	
Drug NDC	00536-3313-00		
Pharmacy			
Drug ID			
Brand Name			
Generic Name	Aspirin		
Strength / Unit	325 mg		
Dosage Form	EC Tab		
Distributor	Rugby		
Shape	Round		
Color Pattern	Solid		
Color	Bright Orange		
Scoring	No Scoring		
Markings	011/P		
Units Per 12 Dram	65		
Storage Loc.	<none selected>		
Product Type	Rx-NDC	DEA Schedule	
<input checked="" type="checkbox"/> Use Front Image Only on Label			
Description		Require Package Code Match on Fill	
Swallow tablet(s) whole. Take with a full glass of water.		Subscribed <input checked="" type="checkbox"/>	
Add		Delete	
		Drug Version # 4	
		Quantity Verification	
		<input checked="" type="radio"/> No recount required <input type="radio"/> Recount / Dispose of excess <input type="radio"/> Recount / Return excess to fill device <input type="radio"/> Recount / Return excess to stock <input type="radio"/> Warn if overcount detected	
		Add	
		Delete	
		OK	
		Cancel	
		Apply	

Drug Data [Main] SP 200/SP 100

Drug Name: Lotensin Benazepril 40 mg Tab Novartis Drug Packages

Drug NDC: 00083-0094-00 Default Label 30 32 90

Pharmacy: [] Drug ID: []

Brand Name: Lotensin

Generic Name: Benazepril

Strength / Unit: 40 mg

Dosage Form: Tab

Distributor: Novartis

Shape: Round

Color Pattern: Solid

Color: Rose

Scoring: No Scoring

Markings: LOTENSIN/40

Units Per 12 Dram: 136

Storage Loc: <none selected>

Product Type: Rx-NDC DEA Schedule: [] Storage Location: <none selected>

Use Front Image Only on Label

Description

Do not take other medicines without your...
Do not take this medication if you are pr...
Medicine may impair your ability to driv...

Add Delete

Require Package Code Match on Fill

Subscribed

Drug Version # []

Add Delete

Quantity Verification

No recount required

Recount / Dispose of excess

Recount / Return excess to fill device

Recount / Return excess to stock

Warn if overcount detected

Add Delete

Package Code: 00083-0094-32 Metric Quantity: 100

Bar Code: 0083009432 User Override Qty: []

Pharmacy Package ID: [] Reorder Code: [] Print Label

Cost: 0.000000

OK Cancel Apply

Drug Data [Main] SP 200/SP 100

Drug Name: Lotensin Benazepril 40 mg Tab Novartis Drug Packages

Drug NDC: 00083-0094-00 Default Label 30 32 90

Pharmacy: [] Drug ID: []

Brand Name: Lotensin

Generic Name: Benazepril

Strength / Unit: 40 mg

Dosage Form: Tab

Distributor: Novartis

Shape: Round

Color Pattern: Solid

Color: Lt. Coral

Scoring: No Scoring

Markings: LOTENSIN/40

Units Per 12 Dram: 136

Storage Loc: <none selected>

Product Type: Rx-NDC DEA Schedule: [] Storage Location: <none selected>

Use Front Image Only on Label

Description

Do not take other medicines without your...
Do not take this medication if you are pr...
Medicine may impair your ability to driv...

Add Delete

Require Package Code Match on Fill

Subscribed

Drug Version # []

Add Delete

Quantity Verification

No recount required

Recount / Dispose of excess

Recount / Return excess to fill device

Recount / Return excess to stock

Warn if overcount detected

Add Delete

Package Code: 00083-0094-32 Metric Quantity: 100

Bar Code: 0083009432 User Override Qty: []

Pharmacy Package ID: [] Reorder Code: [] Print Label

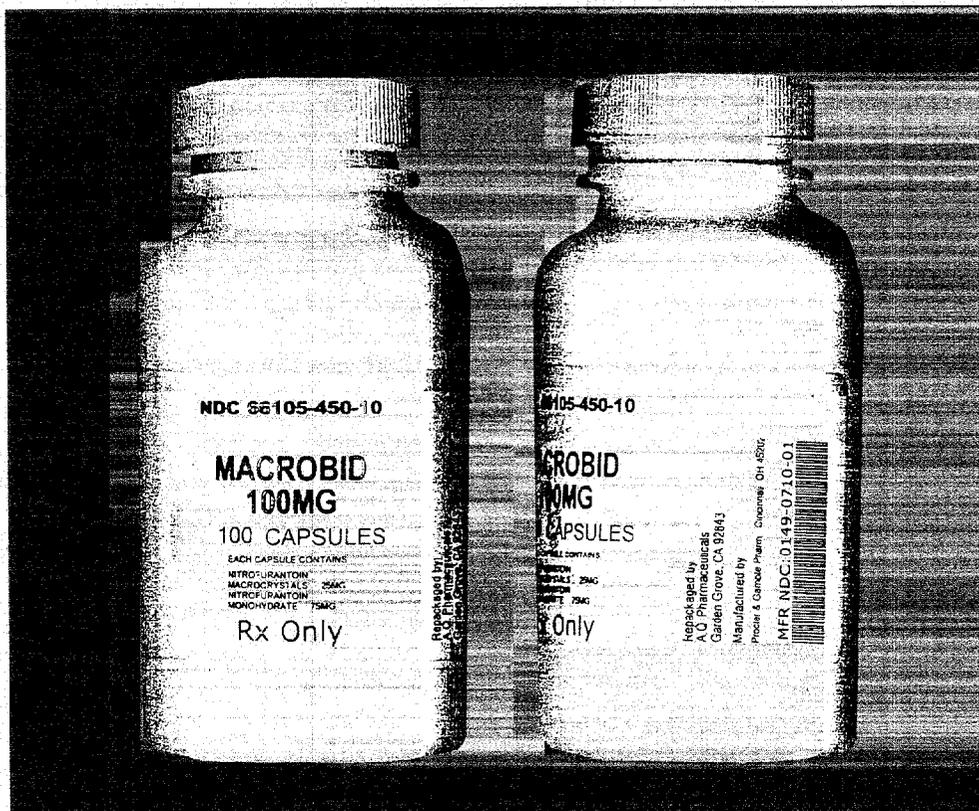
Cost: 0.000000

OK Cancel Apply

From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
Bar Code Label Requirements for Human Drug Products
July 26, 2002, from 9 a.m. to 5 p.m.
Natcher Auditorium, Building 45
National Institutes of Health, Bethesda, MD

**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
BIOLOGIC PRODUCTS**

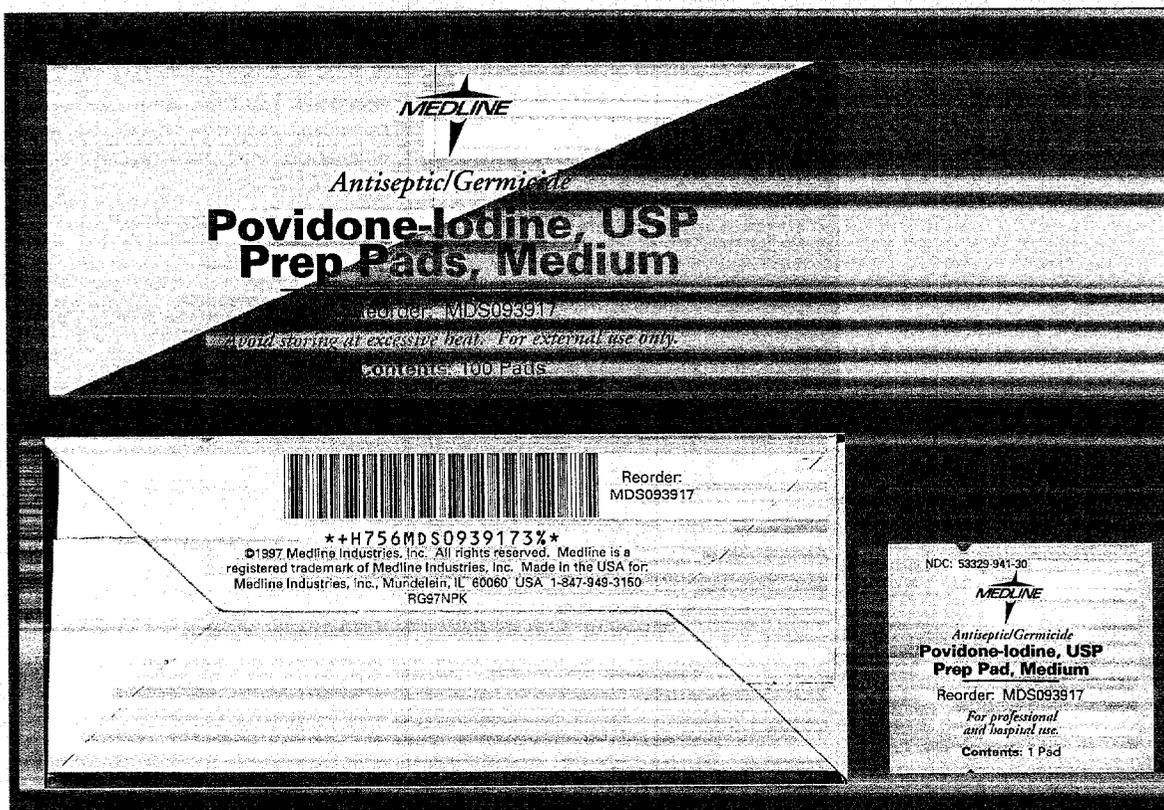
APPENDIX C - DISTRIBUTOR RELABELING PROBLEM



From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
Bar Code Label Requirements for Human Drug Products
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**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
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APPENDIX D - EXTERIOR-INTERIOR PACKAGING PROBLEM



From: Michael E. Coughlin, President and CEO, ScriptPro
 Date: July 26, 2002
 Re: Food and Drug Administration (FDA), HHS, Public Meeting
 Bar Code Label Requirements for Human Drug Products
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**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
 CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
 BIOLOGIC PRODUCTS**

APPENDIX E - BAR CODE AND NDC COMPLETELY DIFFERENT

Drug Data [Main] SP 200/SP 100

Drug Name	Salsalate 750 mg Tab Duramed	Drug Packages	
Drug NDC	51285-0297-00	Default Label	04
Pharmacy			
Drug ID			
Brand Name			
Generic Name	Salsalate		
Strength / Unit	750 mg		
Dosage Form	Tab		
Distributor	Duramed		
Shape	Oblong		
Color Pattern	Solid		
Color	Lt. Aqua		
Scoring	Single-scored		
Markings	dp 297		
Units Per 12 Dram	30		
Storage Loc.	<none selected>		
Product Type	Rx-NDC	DEA Schedule	
		Package Code	51285-0297-01
		Metric Quantity	500
		Bar Code	2817629704
		User Override Qty	
		Pharmacy	
		Package ID	
		Reorder Code	
		Print Label	
		Cost	0.000000
		Storage Location	<none selected>

Use Front Image Only on Label

Description Take with food and a full glass of water.	<input type="checkbox"/> Require Package Code Match on Fill	Add Delete
	<input checked="" type="checkbox"/> Subscribed Drug Version # 1	Quantity Verification <input checked="" type="radio"/> No recount required <input type="radio"/> Recount / Dispose of excess <input type="radio"/> Recount / Return excess to fill device <input type="radio"/> Recount / Return excess to stock <input type="radio"/> Warn if overcount detected

OK Cancel Apply

From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
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**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
BIOLOGIC PRODUCTS**

APPENDIX F - DIFFERENT 11-DIGIT NDCs PRODUCE SAME 10-DIGIT NDC

11-DIGIT NDC (1ST PRODUCT)
11-DIGIT NDC (2ND PRODUCT)
10-DIGIT NDC (SAME FOR BOTH)

11845011855 FAT BLOCKER PLUS TABLET
11845118505 CITRIMAX 500 PLUS TABLET
1184511855

52959010220 METRONIDAZOLE 500MG TABLET
52959102200 BETAMETHASONE VA 0.1% CREAM
5295910220

52959011330 BACITRACIN ZINC OINTMENT
52959113300 TRIAMCINOLONE 0.5% CREAM
5295911330

52959014103 ACETAMINOPHEN/COD ELIXIR
52959141003 PROMETHAZINE/CODEINE SYRUP
5295914103

52959014410 SULFAMETHOXAZOLE/TMP DS TAB
52959144100 SANTYL OINTMENT
5295914410

52959014420 SULFAMETHOXAZOLE/TMP DS TAB
52959144200 BACITRACIN ZINC OINTMENT
5295914420

52959014500 ISONIAZID 300MG TABLET
52959145000 FLUOCINONIDE 0.05% OINTMENT
5295914500

58016010321 AMOXICILLIN 250MG CAPSULE
58016103201 AMPICILLIN 125MG/5ML SUSP
5801610321

58016031421 NAPROXEN 250MG TABLET
58016314201 RETIN-A 0.05% CREAM
5801631421

58016075230 LOPERAMIDE 2MG CAPSULE
58016752300 BENZTROPINE MES 2MG TABLET
5801675230

From: Michael E. Coughlin, President and CEO, ScriptPro
 Date: July 26, 2002
 Re: Food and Drug Administration (FDA), HHS, Public Meeting
 Bar Code Label Requirements for Human Drug Products
 July 26, 2002, from 9 a.m. to 5 p.m.
 Natcher Auditorium, Building 45
 National Institutes of Health, Bethesda, MD

**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
 CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
 BIOLOGIC PRODUCTS**

APPENDIX G - BAR CODE TRANSLATION TO NDC PROBLEM

Drug Data

Main | SP 200/SP 100

Drug Name Xanax Alprazolam 2 mg Tab Pharmacia Drug Packages

Drug NDC	00009-0094-00	Default	Label	01	03		
Pharmacy							
Drug ID							
Brand Name	Xanax						
Generic Name	Alprazolam						
Strength / Unit	2 mg						
Dosage Form	Tab						
Distributor	Pharmacia						
Shape	Rectangular						
Color Pattern	Solid						
Color	White						
Scoring	Six-scored						
Markings	2/XANAX						
Units Per 12 Dram	71						
Storage Loc.	<none selected>						
Product Type	Rx-NDC					DEA Schedule	IV
<input checked="" type="checkbox"/> Use Front Image Only on Label		Bar Code	0009009401	User Override Qty		<input type="button" value="Print Label"/>	
Description Avoid alcoholic beverages. May cause drowsiness.		Pharmacy		Package ID		Reorder Code	
<input type="button" value="Add"/> <input type="button" value="Delete"/>		Cost	0.000000	Storage Location	<none selected>	<input type="checkbox"/> Require Package Code Match on Fill <input checked="" type="checkbox"/> Subscribed Drug Version # 1	
		Quantity Verification		<input checked="" type="checkbox"/> No recount required <input type="checkbox"/> Recount / Dispose of excess <input type="checkbox"/> Recount / Return excess to fill device <input type="checkbox"/> Recount / Return excess to stock <input type="checkbox"/> Warn if overcount detected			
		<input type="button" value="OK"/> <input type="button" value="Cancel"/> <input type="button" value="Apply"/>					

Main		Drug Packages				
Drug Name	Alprazolam 1 mg Tab Greenstone		01	03	04	
Drug NDC	59762-3721-00		Default	Label		
Pharmacy	[Dropdown]		[Image: Two bottles of Alprazolam 1 mg tablets]			
Drug ID	[Dropdown]					
Brand Name	[Dropdown]					
Generic Name	Alprazolam					
Strength / Unit	1 mg					
Dosage Form	Tab					
Distributor	Greenstone					
Shape	Oval					
Color Pattern	Mottled					
Color	Lt. Blue		Package Code	59762-3721-01	Metric Quantity	100
Scoring	Single-scored		Bar Code	5976237211	User Override Qty	[Dropdown]
Markings	G 3721		Pharmacy	[Dropdown]	[Print Label]	
Units Per 12	224		Package ID	[Dropdown]		
Dram	[Dropdown]		Reorder Code	[Dropdown]		
Storage Loc.	<none selected>		Cost	0.000000		
Product Type	Rx-NDC	DEA Schedule	IV	Storage Location	<none selected>	
<input checked="" type="checkbox"/> Use Front Image Only on Label						
Description Avoid alcoholic beverages. May cause drowsiness.		<input type="checkbox"/> Require Package Code Match on Fill <input checked="" type="checkbox"/> Subscribed Drug Version # [1]		Quantity Verification <input checked="" type="radio"/> No recount required <input type="radio"/> Recount / Dispose of excess <input type="radio"/> Recount / Return excess to fill device <input type="radio"/> Recount / Return excess to stock <input type="radio"/> Warn if overcount detected		Add Delete
[Add] [Delete]		[Left Arrow] [Right Arrow]		[OK] [Cancel] [Apply]		

From: Michael E. Coughlin, President and CEO, ScriptPro
 Date: July 26, 2002
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APPENDIX H - PACK SIZE INDICATES PROPERTY OF PRODUCT

Drug Data

Main

Product Name: Yale Needles Needles 22G/1.5 inch Needle B-D

Product Code: 08290305156

Pharmacy: []

Product ID: []

Brand Name: Yale Needles

Generic Name: Needles 22G/1.5 inch

Strength / Unit: []

Dosage Form: Needle

Distributor: B-D

Shape: []

Color Pattern: []

Color: []

Scoring: []

Markings: []

Units Per 12: []

Dram: []

Storage Loc.: <none selected>

Product Type: Supply

DEA Schedule: []

Product Packages

Default Label: 08290305156

Package Code: 08290305156

Bar Code: *H1803051563

Metric Quantity: 100

User Override Qty: []

Pharmacy: []

Package ID: []

Reorder Code: []

Cost: 0.000000

Storage Location: <none selected>

Use Front Image Only on Label

Print Label

Description: []

Require Package Code Match on Fill:

Subscribed:

Drug Version #: 1

Quantity Verification:

- No recount required
- Recount / Dispose of excess
- Recount / Return excess to fill device
- Recount / Return excess to stock
- Warn if overcount detected

Add Delete

OK Cancel Apply

Drug Data

Main

Product Name **Yale Needles Needles 21G/1 inch Needle B-D** Product Packages

Product Code **08290305165** Default Label **08290305165**

Pharmacy **[dropdown]**

Product ID **[dropdown]**

Brand Name **Yale Needles**

Generic Name **Needles 21G/1 inch**

Strength / Unit **[dropdown]**

Dosage Form **Needle**

Distributor **B-D**

Shape **[dropdown]**

Color Pattern **[dropdown]**

Color **[dropdown]**

Scoring **[dropdown]**

Markings **[dropdown]**

Units Per 12 **[dropdown]**

Dram **[dropdown]**

Storage Loc. **<none selected>**

Product Type **Supply** DEA Schedule **[dropdown]** Storage Location **<none selected>**

Use Front Image Only on Label

Description **[empty box]**

Add **Delete**

Require Package Code Match on Fill

Subscribed

Drug Version # **[dropdown]**

Quantity Verification

No recount required

Recount / Dispose of excess

Recount / Return excess to fill device

Recount / Return excess to stock

Warn if overcount detected

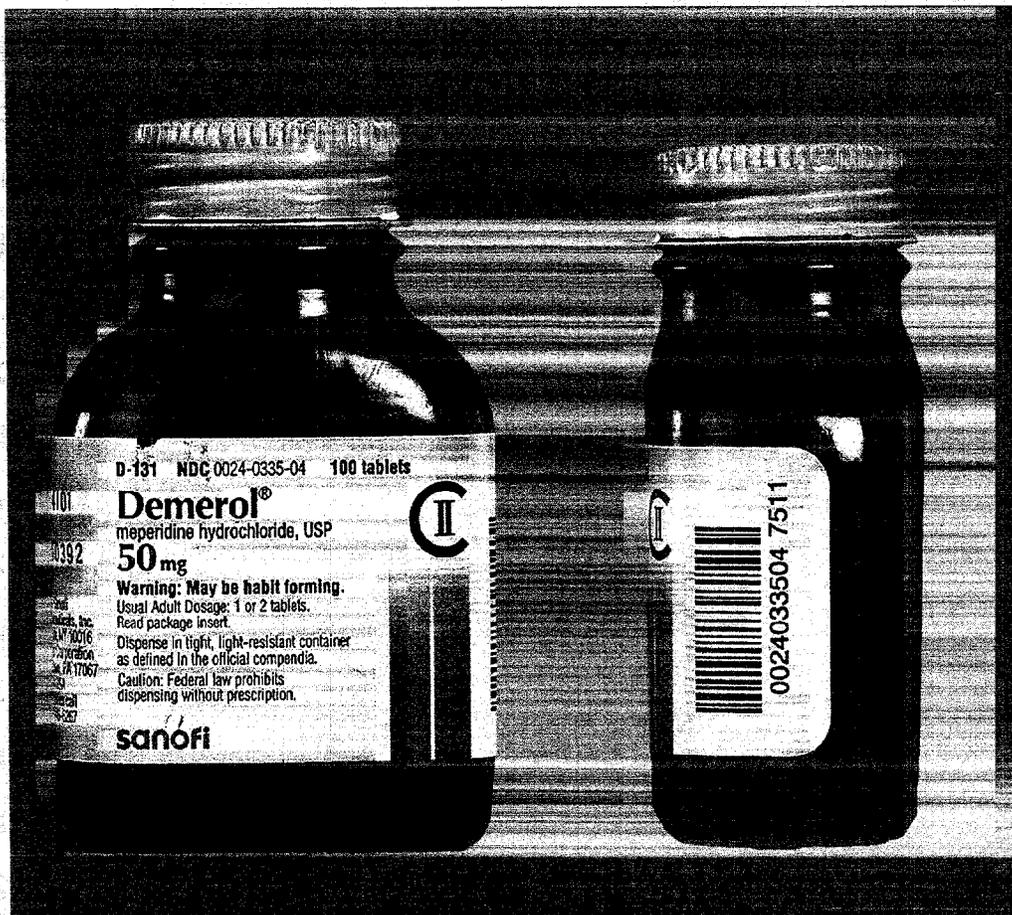
Add **Delete**

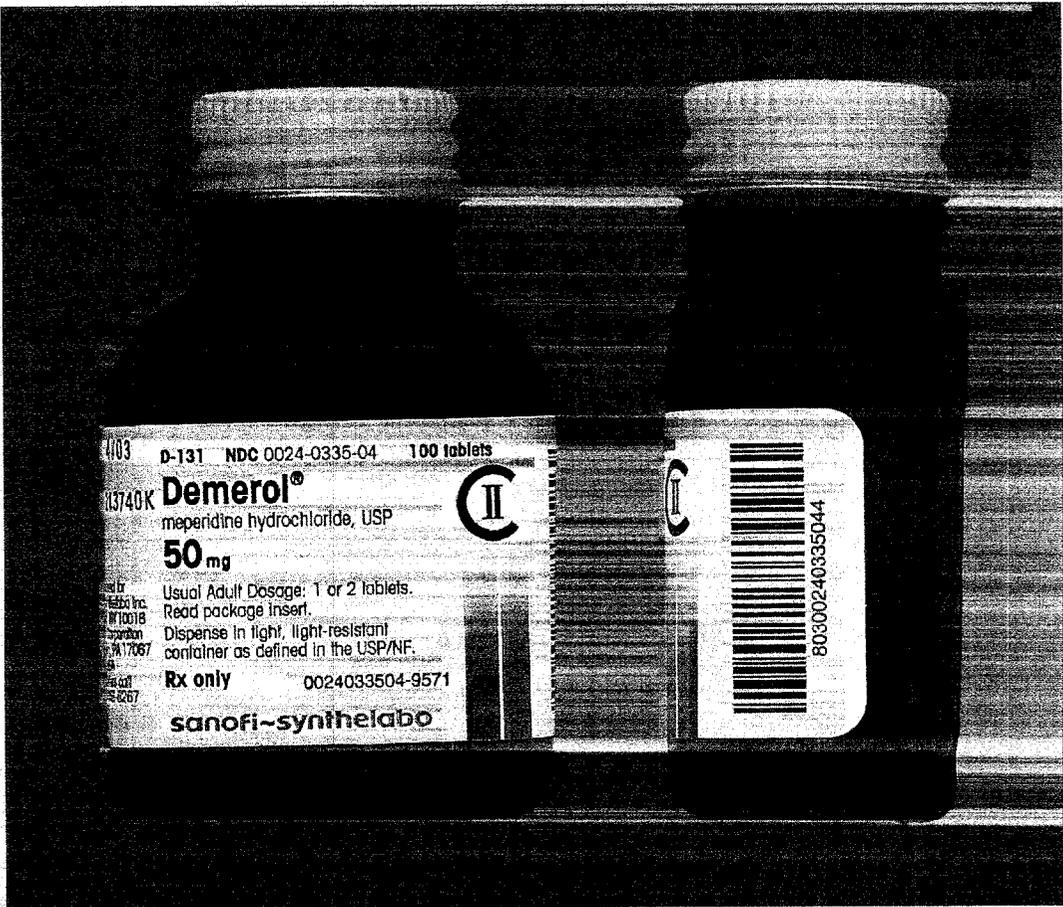
OK **Cancel** **Apply**

From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
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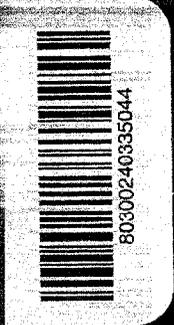
**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING
BIOLOGIC PRODUCTS**

APPENDIX I - MULTIPLE BAR CODES REFERENCE SAME DRUG





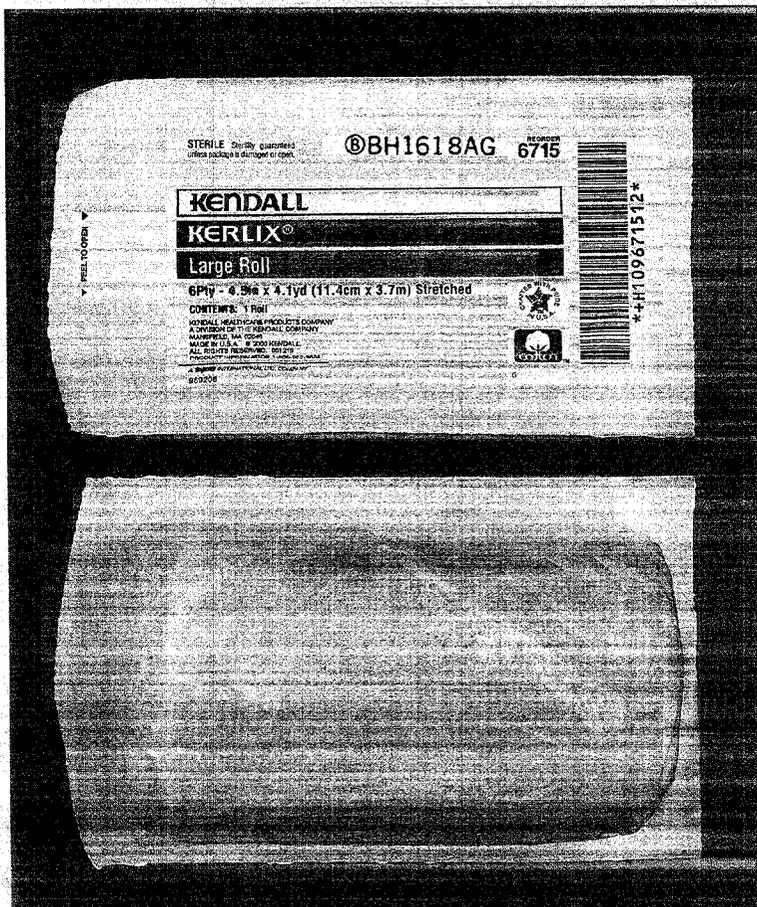
4103 D-131 NDC 0024-0335-04 100 tablets
 13740K **Demerol**[®]
 meperidine hydrochloride, USP 
50 mg
 Usual Adult Dosage: 1 or 2 tablets.
 Read package insert.
 Dispense in light, light-resistant
 container as defined in the USP/NF.
Rx only 0024033504-9571
sanofi-synthelabo

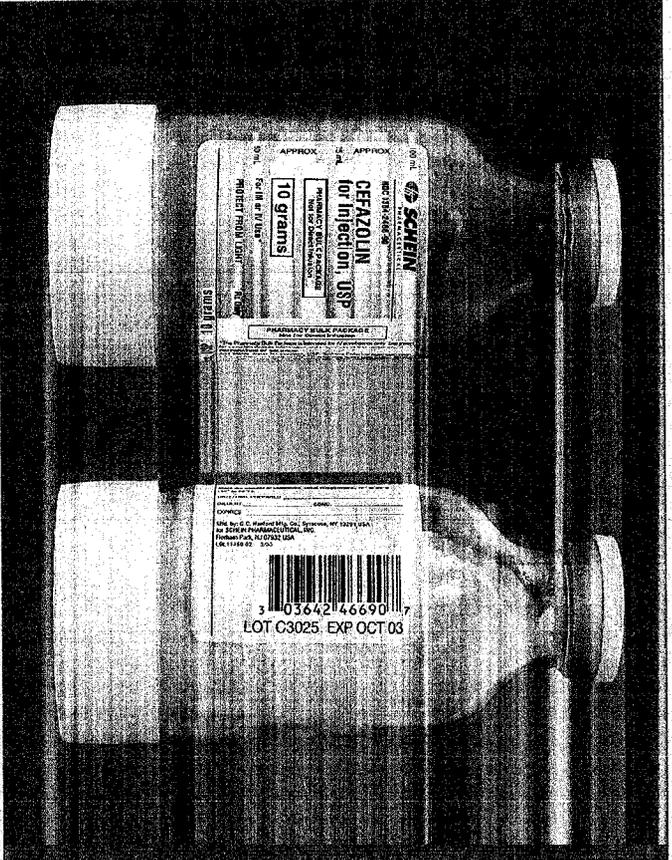
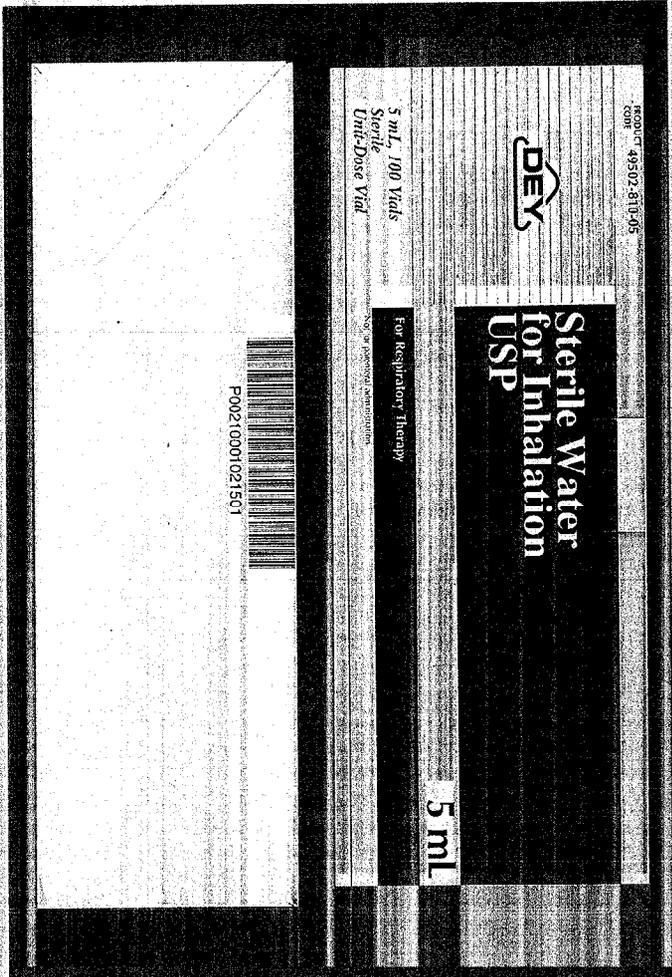


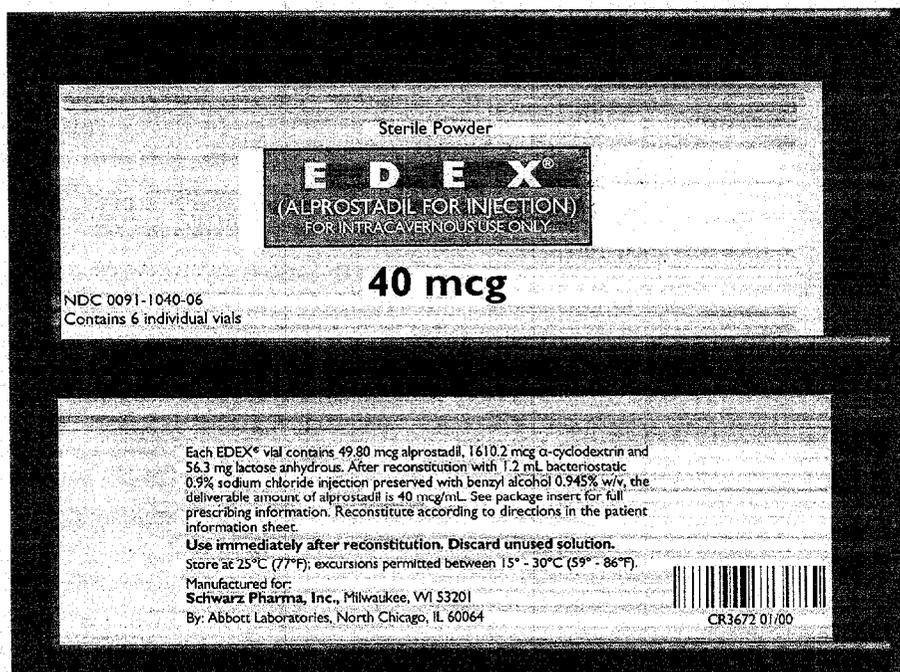
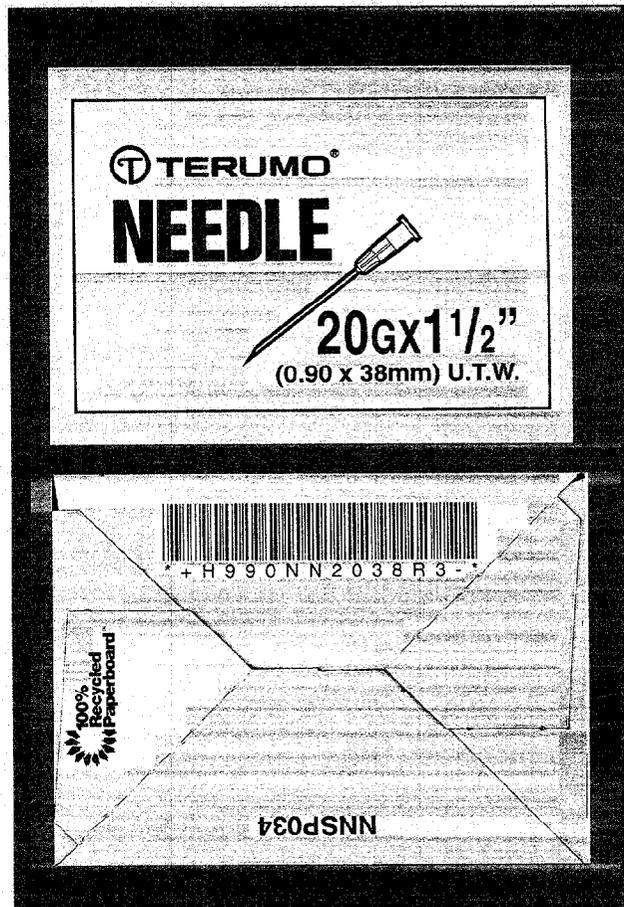
From: Michael E. Coughlin, President and CEO, ScriptPro
Date: July 26, 2002
Re: Food and Drug Administration (FDA), HHS, Public Meeting
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**RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR
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APPENDIX J - VARIOUS TYPES OF BAR CODES ON DRUGS







mepore®

9 x 30 cm/3.6 x 12 in

30 pcs

STERILE EO



(01)07310791014081



PZN-3137455

en Adhæsiivapuhdas
de Klebefläche
fr Pression
es Adhesión
it Adesione
nl Plak
da Klæber
sv Klämningsyta
pt Adesão
pl Adhezyja
ru Adгезия
no Adhæsion
fi Adheesio

mepore
9 x 30 cm/3.6 x 12 in
REF 671302
802024



PZN 727051

STERILE EO

Mölnlycke Health Care AB

en Check every 10 minutes
de Überprüfen Sie alle 10 Minuten
fr Vérifier toutes les 10 minutes
es Comprobar cada 10 minutos
it Controllare ogni 10 minuti
nl Controleer elke 10 minuten
da Tjek alle 10 minutter
sv Kontrollera varje 10 minuter
pt Verificar a cada 10 minutos
pl Sprawdzaj co 10 minut
ru Проверять каждые 10 минут
no Sjekk alle 10 minutter
fi Tarkista joka 10 minuuttia

mepore
9 x 30 cm/3.6 x 12 in
REF 671300



30 pcs

STERILE EO

Mölnlycke Health Care AB

en Adhesive surgical drape
de Klebefläche
fr Pression
es Adhesión
it Adesione
nl Plak
da Klæber
sv Klämningsyta
pt Adesão
pl Adhezyja
ru Adгезия
no Adhæsion
fi Adheesio

mepore
9 x 30 cm/3.6 x 12 in
REF 671302
802024



PZN 727051

STERILE EO

Mölnlycke Health Care AB

Extra Strength TYLENOL®

Pain Reliever - Fever Reducer ACETAMINOPHEN

Tablets



60 TABLETS
500 mg each

THIS PRODUCT IS FOR PAIN RELIEF AND FEVER REDUCTION ONLY. IT IS NOT INTENDED FOR CHILDREN.

SEE NEW LABEL

Active Ingredient (In Each Tablet):
Acetaminophen 500 mg

Purpose:
Pain Reliever/Fever Reducer

Uses:

- For the temporary relief of minor aches and pains associated with:
 - headache • muscular aches • backache • minor arthritis pain
 - common cold • toothache • menstrual cramps
- For the reduction of fever.

Warnings:

Alcohol Warning: • If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do Not Use:

- with any other product containing acetaminophen
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Stop Using and Ask a Doctor If:

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- redness or swelling is present



3 0045-0499-68 4

EXP:

Extra Strength TYLENOL®

Pain Reliever - Fever Reducer ACETAMINOPHEN

Tablets



100 TABLETS - 500 mg each

The makers of TYLENOL® do not manufacture store brands.



3 0045-0499-60 8

EXP:

06 / C 5

BarA-Us 0

Drug Facts (continued)

Directions

• do not take more than directed

adults and children 12 years and over	• take 2 tablets every 4 to 6 hours as needed
children under 12 years	• do not take more than 8 tablets in 24 hours

do not use this adult Extra Strength product in children under 12 years of age; this will provide more than the recommended dose (amount) of TYLENOL® and could cause serious health problems.

Other information

- do not use if carton is opened or red neck wrap or foil liner seal imprinted with "Safety Seal" is broken
- store at room temperature
- see end panel for lot number and expiration date

Inactive ingredients

cellulose, corn starch, magnesium stearate, sodium starch glycolate

Questions or comments?

call toll-free 1-877-TYLENOL (1-877-585-3685)

How TYLENOL® Products Are Different:

- Recommended the most by doctors and used the most by hospitals.

- Aspirin free. Unlikely to cause the gastric irritation often associated with aspirin, naproxen sodium or even ibuprofen.

The makers of TYLENOL® do not manufacture store brands.

Extra Strength TYLENOL

Pain Reliever + Fever Reducer
ACETAMINOPHEN

Adult Liquid



SEE NEW LABEL

Extra Strength TYLENOL

Pain Reliever + Fever Reducer
ACETAMINOPHEN

Adult Liquid

Active Ingredient:
(in Each 30 mL & 2 Tablespoonful)
Acetaminophen 1000 mg

Purpose:
Pain Reliever/Fever Reducer

Uses:

- For the temporary relief of minor aches and pains associated with:
 - headache • muscular aches • backache • minor arthritis pain
 - common cold • toothache • menstrual cramps
- for the reduction of fever

Warnings:

Alcohol Warning:
If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do Not Use:

- with any other product containing acetaminophen
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Stop Using and Ask a Doctor If:

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- redness or swelling is present

Do not exceed recommended dose. Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a physician or poison control center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Store at room temperature.
See bottom for expiration date.

Extra Strength TYLENOL

Pain Reliever + Fever Reducer
ACETAMINOPHEN

Adult Liquid

Directions:

Adults and children 12 years of age and older:	Take 2 Tablespoons (tbsp.) in dose cup provided every 4 to 6 hours as needed. Do not take more than 8 Tablespoons in 24 hours, or as directed by a doctor.
Children under 12 years:	Do not use this adult Extra Strength product in children under 12 years of age. This will provide more than the recommended dose (overdose) of TYLENOL and could cause serious health problems.

Do not use if carton is opened, or if bottle wrap or foil inner seal imprinted "Safety Seal" is broken or missing.

Inactive Ingredients: Alcohol 17%, Citric Acid, D&C Yellow #10, FD&C Blue #1, FD&C Yellow #6, Flavor, Glycerin, Polyethylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Sucrose.



3 0045-0500-08 3

Extra Strength TYLENOL

Pain Reliever + Fever Reducer
ACETAMINOPHEN

Tablets

30 TABLETS - 500 mg each



The name of TYLENOL is a registered trademark of Parke-Davis.

Drug Facts

Active Ingredient (in each tablet)	Purposes
Acetaminophen 500 mg	Pain reliever/fever reducer

Uses: temporarily relieves minor aches and pains due to:

- headache
- backache
- the common cold
- menstrual cramps
- muscular aches
- arthritis
- toothache

Warnings:

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use with any other product containing acetaminophen.

Stop use and ask a doctor if:

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days



3 0045-0499-32 5

EXP: _____

EA0069

From: Michael E. Coughlin, President and CEO, ScriptPro
 Date: July 26, 2002
 Re: Food and Drug Administration (FDA), HHS, Public Meeting
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**APPENDIX K - TWO DIFFERENT DRUGS APPEAR AS ONLY DIFFERENT
 PACKAGE SIZES**

1. The example below shows the following:
 - a. The field labeled NDC is the 11-digit drug identifier provided by FirstDataBank, Inc. in its National Drug Data File (NDDF). Most pharmacy computer applications use the NDDF to perform Drug Utilization Reviews and adjudicate prescription claims. The NDDF is also used by payors to pay prescription claims.
 - b. The three drug entries (see picture below) appear from their numbers to be three different package sizes for the same drug. This is because the numbers are identical except for the last two characters, which designate package size.
 - c. However, as listed in the GNN (Generic Name) column, the third entry is a completely different drug.
 - d. This problem was discovered simply by chance in developing the data for this report. We believe that the source of the problem is an error in the placement of the zero in order to expand the 10-digit NDC to 11 digits. For the third entry, the additional zero probably should have been placed in front of digits 32 instead of behind them.

NDC	GNN	LN	MFG	NDC10
61808032001	ISOSORBIDE DINITRATE	ISOSORBIDE DN 20MG TABLET	IMIREN PHARM	6180832001
61808032010	ISOSORBIDE DINITRATE	ISOSORBIDE DN 20MG TABLET	IMIREN PHARM	6180832010
61803032003	SULFAMETHOXAZOLE/TRIMETHOPRIM	SULFAMETHOXAZOLE/TMP DS TAB	IMIREN PHARM	6180832005