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Bar Code Label Requirements for Human Drug Products

Docket No. 02N-0204

Public Meeting
Friday, July 26, 2002
William H. Natcher Conference Building
National Institutes of Health
Building 45
Bethesda, MD.

Comments of:
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02N-0204

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Returns Online, Inc. provides comprehensive recall management services to manufacturers, distributors and retailers of pharmaceutical and medical device products. Our significant investment in technology and product development coupled with years of experience in recall management ensures a reliable and complete solution.

Returns Online, Inc. and its clients rely on precise and very timely information. As such, Returns Online has invested millions of dollars in creating the technology platform and facilities infrastructure to provide this critical data as quickly and accurately as possible. Our many years of experience in the pharmaceutical recall and returns industry and the considerable research completed to create our state of the art infrastructure uniquely qualify us to comment on the proposed bar code labeling requirements being studied.

Returns Online, Inc. commends and supports the development of a regulation on bar code labeling for human drug products and medical devices for the following reasons:

Any human drug product (including OTC products) that will be administered or dispensed to the public should contain a bar code that identifies the drug product (utilizing the NDC Number), the lot number of the batch and the expiration date of the product. To enforce this stance, consider how accuracy could be improved in the distribution of the product, the dispensing of the product and if necessary the recall of the product.

The manufacturer and/or the distributor would have the ability to scan the product at the time of order picking and assure accurate order fulfillment by cross checking the pulled product as compared to the product ordered. This scan process also would record the lot number of the product thereby creating a database that could be utilized as a reference for targeted notifications in the event of a recall.

The pharmacist, on the other hand, would be able to scan the bottle or package to also assure that the product picked is the product ordered on the prescription. This again would give the dispensing system the ability to automatically record the lot number and expiration date.

Both the distribution and pharmacy software could have the ability to carry a database of recalled product by lot number that could flag the product picked as a previously recalled product that should not be distributed or dispensed. A recall event is a one time event for individual lot numbers and unfortunately if a recalled product is missed, the current systems do not flag previously recalled



product to the pickers because, in most cases, the lot numbers are not recorded anyway.

It is understood that the above scenario could be handled by manually entering the lot numbers at each distribution or dispensing, however, lot numbers are not easily captured manually due to the methods of applying, the variance of formats (some up to 10 alpha and numeric characters) and the human element of mis-entering a single digit. This cross check against a database of previously recalled lot numbers could possibly save enough human suffering or death to warrant the expenditure to implement the systems to monitor lot numbers.

CONCLUSION: There are numerous, far-reaching benefits to expanding current bar code labeling requirements for pharmaceuticals and medical devices. As it pertains to safety recall management specifically, bar code labeling lot numbers and expiration dates enhances the accuracy and time efficiencies to monitor and assess the effectiveness of a recall event. Additionally, automation can improve the identification and segregation of recalled product to prevent further distribution, safeguarding the public against the dangers of receiving and utilizing recalled product.

We welcome the opportunity to comment further on this notice and if appropriate meet with you to discuss these issues.

Sincerely,

Billy H. Snipes, R.Ph.
Executive Vice President
Returns Online, Inc.