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January 26, 2007

Division of Dockets Management (HFA-305)  
United States Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Submission of written comments to FDA regarding "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application and Animal Drugs. Docket Number 2005N-0403 [71 Fed. Reg. 51276, August 29, 2006]

Dear Sir or Madam:

On behalf of CVS/pharmacy, I respectfully submit the following comments to the FDA (Docket Number: 2005N-0403).

### **Introduction**

CVS is America's largest retail pharmacy, operating more than 6,200 retail and specialty pharmacy stores in 43 states and the District of Columbia. CVS innovatively serves the healthcare needs of all customers through its CVS/pharmacy stores; its online pharmacy, CVS.com; its retail-based health clinic subsidiary, MinuteClinic; and its pharmacy benefit management, mail order and specialty pharmacy subsidiary, PharmaCare.

CVS acknowledges the importance of the FDA's efforts to clarify its regulations governing drug establishment registration and listing. While CVS supports much of the proposed rule, some elements, specifically those related to retail service repackagers and the use of their own NDC on each repackaged product are of concern.

Community pharmacies heavily depend upon product NDC numbers throughout the associated workflow of filling patient prescriptions; from the product selection, to prescription entry into dispensing systems, to final prescription reviews. NDC numbers are the key data element in prescription filling, prescription processing, and quality assurance. The FDA's proposed rule for repackaged product will jeopardize the practical functionality of the NDC number, as single products will have multiple NDC numbers.

Additionally, for the repackager's NDC to be used by community pharmacies that NDC would have to be recognized by database companies, PBMs, insurance companies, Medicaid, and

individual pharmacy systems. Today, these critical components of the pharmacy operations and claims adjudication processes do not recognize repackager NDC's.

The issues below highlight some of the negative effects this rule may have on community pharmacies. Each issue, whether operational or systemic, will have an impact on patient safety and patient access to needed medication.

**Pharmacy confusion regarding NDC numbers:** Significant confusion will be caused under the proposed rule since a single product may have multiple distinct NDC numbers depending whether that product is repackaged or not. Pharmacists will be required to inefficiently and manually choose among multiple NDC options for the same product. Additionally, uncertainty at the pharmacy level will arise regarding the correct NDC to use for prescription processing as well as insurance claim adjudication and patient safety cross referencing. Bearing in mind, repackager NDC's are not utilized in these processes. Training pharmacy staff will not be effective given the number of products that are available in repackaged form as well as the large number of people who will need to be trained. Therefore, compliance in utilizing the correct NDC cannot be guaranteed.

**Product Selection and Data Entry:** Manufacturer NDC numbers are being used today as the product identifier within community pharmacy. For instance, the product's NDC is used as the driver for product selection on the pharmacy shelf, prescription entry into the pharmacy dispensing system, and final prescription review by the Pharmacist prior to releasing the prescription to the patient. These processes become less efficient and prone to potential error, causing a detrimental impact to patient safety, if the repackager's unique NDC is the NDC referenced on the product. Options to mitigate this risk such as linking the repackager's NDC to the manufacturer's NDC systemically pose their own hurdles that may actually increase the risk to patient safety. Specifically, failure to accurately and timely maintain the links from all the repackager's NDC(s) to the manufacturer's NDC will decrease the value of all patient level safety processes.

**Drug Interaction/Utilization reviews:** Each prescription filled at a CVS pharmacy is compared to the patient's profile to perform various patient level safety checks and drug use reviews such as: drug allergies, appropriate dosing, adverse reactions with other medication the patient is prescribed, and therapeutic duplications. These reviews are essential to patient safety throughout community pharmacy. The manufacturer NDC number is the unique product identifier that is used to perform these reviews. The manufacturer NDC provides added assurance of the proper drug reviews; if the repackager's NDC is the only NDC on the product, this ability is eliminated.

**Automated Replenishment Systems:** Most community pharmacies are now managing their pharmacy inventory with automated replenishment systems to limit unnecessary inventory while at the same time ensuring necessary product is available for patients. These systems are maintained at, and driven from, the manufacturer's NDC number for each product. The systems anticipate the demand at the NDC level of each product and replenish each item based on this demand. The effect of the proposed rule on inventory management systems may represent a technological hurdle since demand may be scattered across multiple NDC numbers for the same product, potentially causing understated demand and insufficient supply of needed product.

**Drug Returns:** It has been said that the use of the repackager's NDC may aid in product identification during emergencies, such as drug recalls. In actuality the use of the repackager's NDC will add complexity and potential error to recall processes at community pharmacies. The NDC is the first critical data point that is used in identifying product that is subject to a recall action, which is followed by lot number and expiration date. Currently, there is a direct one product to one NDC relationship between the recalled product and the NDC that identifies it. Under the proposed rule, this relationship changes into a one product to, potentially, many NDC ratio. By making the drug recall process more complex the chances for errors increases significantly, the result of which is a system that is less efficient and accurate and can potentially create a public health risk.

The FDA's proposed rule, as it relates to repackaged product, would not serve to enhance patient safety within community pharmacy, but would in actuality be detrimental to patient safety. For this reason, as well as the technological hurdles this rule creates, CVS requests the FDA consider other alternatives to the use of repackager's NDC. These alternatives include, requiring retail service repackaging companies include their unique Repack Item Code (RIC) to repackaged product in human readable format.

I thank you for your consideration of these comments. The CVS organization is willing to avail itself to the FDA for any additional assistance, input, or information that it may need regarding this issue. Please contact me directly at (401) 770-3402 if I may be of further assistance.

Sincerely,

A handwritten signature in black ink, reading "Matthew J. Leonard". The signature is written in a cursive style. To the right of the signature is a vertical red line.

Matthew J. Leonard, R.Ph.  
Senior Vice President, Pharmacy