NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

January 26, 2007

Department of Health and Human Services
Food and Drug Administration
Division of Dockets Management HFA-305
Docket No. 2005N-0403/RIN 0910-AA49
5630 Fishers Lane Room 1061
Rockville, Maryland 20852

Subject: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs

To Whom to May Concern:

The National Association of Chain Drug Stores (NACDS) is pleased to provide comments to the Food and Drug Administration (FDA) regarding the agency's proposals to change the way that manufacturers register and list their facilities and regulated products with the agency, as well as the way that National Drug Code (NDC) numbers are assigned and used.

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NACDS is the national trade association representing companies that operate 35,000 community-based retail pharmacies. Our members include small and large chain operated pharmacies, such as traditional chain drug stores, supermarket pharmacies and mass merchandise pharmacies. Our membership collectively dispenses almost 70 percent of all retail prescriptions in the United States.

We agree that there are many technological benefits to a more efficient and logical process for assigning NDC numbers. Having said that, NACDS also believes that this proposed regulation is highly complex and that will have profound patient care, economic, and administrative consequences for the health care distribution system.

For that reason, we urge that the agency consider implementing these changes in phases. We urge that the drug registration and listing modifications be made first, followed by some of the proposed NDC number changes. We also believe that the proposed rule's economic analysis substantially underestimates the economic impact that this regulation will have on the pharmaceutical distribution system, including the potential elimination of the retail pharmacy service repackaging industry.

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Summary of Comments

- There is a systematic rationality to the current NDC number code – with the first digits representing the label or manufacturer, the next representing the product, and the final digits representing package size. Relative to with the tens of thousands of products in the market, this NDC scheme is working well and has been programmed into the thousands of pharmacy-based computer systems in operation today. We are concerned that the proposed regulation would give FDA the responsibility for assigning these NDC numbers.

- Changes to NDC numbers affect retail pharmacy operators in many different ways. The entire pharmacy distribution system runs off the NDC number. Any changes to the number could affect our ability to operate our basic business model. However, changes also affect retail pharmacies as purchasers of repackaged drugs, as sellers of medical equipment and supplies (such as diabetic testing supplies), as private label distributors of over the counter products, and as warehousing distributors of pharmacy-related products.

- We have to be sure that changes to the current rational basis of the NDC number do not compromise patient safety. Pharmacists use the current NDC numbers to reduce potential medical errors because NDC numbers help pharmacists visually identify products. Current NDC numbers are programmed into existing software systems to detect potential drug interactions. For these reasons, we urge the agency to continue to allow retail pharmacy service repackagers to put the originator manufacturer's NDC number on the repacked drug rather than the repackager's own NDC number.

- Over time, pharmacists become familiar with the labeler code section of the NDC number, and are able to identify the products if the information is included on the actual pharmaceutical product. This patient safety check could be eliminated through draconian changes to the current NDC numbering system.

Part 201 – Labeling

This section specifies the drugs that must have an NDC, the NDC number that is appropriate for the drug label, and other specifics relating to the use of the NDC number.

Section 201.2 - Impact on Repackaged Drugs

NACDS supports the proposed requirement that human-readable NDC numbers appear on the labels of drugs subject to the drug listing requirements.

However, the agency should be aware that there are negative economic, operational, and patient safety implications with requiring that the "appropriate NDC number"' that appears on the drug labels is actually the NDC number of the last manufacturer, repacker or relabeler (including a drug product salvager who repacks or relabels the drug), or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer. We ask that the agency continue to allow for an exemption from this requirement for prescription medications repackaged for retail pharmacies dispensed by the retail pharmacy service repackaging industry, or this entire segment of the pharmaceutical marketplace may be eliminated.

That is, drugs that are repackaged for retail distribution should be able to continue to bear the NDC number of the originator manufacturer. Without this exemption, we are concerned about the following:

- The retail pharmacy supply, dispensing, payment, return goods reverse logistics, and reimbursement systems will not be able to be modified without excessive cost, delay and potential for new system errors.

- The requirement that retail pharmacy repackaged drugs obtain and use their own NDC numbers will introduce a significant number of new NDCs into the marketplace and require expensive reprogramming of pharmacy inventory and processing systems.

- Mandatory use of repackager NDC numbers will eliminate potential transactional efficiencies and hinder third-party reimbursements; increase potential for medication errors and diminish benefits to patient safety; create added complexity to the drug recall process; and, trigger Medicaid drug rebate requirements to the detriment of retail repackagers, States, and the Federal government.

Today, as the result of longstanding FDA guidance and universal commercial practice, retail pharmacy supply, dispensing, payment and reimbursement systems rely upon use of the original manufacturer's NDC number. Retail pharmacy computer systems use the original manufacturer's NDC number to identify the product being dispensed. At this time, in the retail pharmacy setting, repackager NDC numbers are not used in these systems, nor can these systems be modified to accommodate use of such numbers without lost savings and efficiencies, substantial costs, delay and unnecessary potential for system errors affecting patient safety.

For the NDC numbers of retail pharmacy service repackagers to be used, each drug would have to be assigned an NDC number, and this number would have to be maintained by the repackagers and recognized by database companies, PBMs, insurance companies, Medicaid, and pharmacy software systems. This is generally not the case now. That is because the entire pharmacy distribution system has been using the originator manufacturer's number for these billing purposes. Pharmacies do not want to be placed in the position of dispensing one repackager's product but billing for the originator because that would be the only product recognized by the system.

Introduction of these multiple retail pharmacy service repackagers NDC numbers into the marketplace, for which no reimbursement metrics exists (i.e. AWP, WAC, etc.) would create significant disruption in the pharmacy supply chain. Pharmacies cannot bill and payers cannot reimburse without these metrics, which these repackagers do not establish, and are not included in pharmaceutical pricing database sources, such as First Data Bank and Medi-Span.

Moreover, there are literally dozens of diverse systems used by the retail pharmacy sector, ranging from highly sophisticated, integrated nationwide information systems to numerous unique, stand-alone systems used by independent pharmacies. The cost of reprogramming these systems would be staggering, far more than the estimate made in the proposed rule. In addition, listing retail pharmacy repackaged products manually would introduce another measure of error into the patient safety system, since all these repackaged products would have to be manually linked and continuously updated.

We ask that the agency in the final regulation continue the current exemption that it has traditionally provided to a specific class of repackagers - retail pharmacy service repackagers. We are not asking for the agency to grant a broad exemption for all repackagers from the requirement that they use their own NDC number. Most other repackagers are acting more like manufacturers than they are traditional retail pharmacy service repackagers. They should be required to place their own NDC numbers on the label. We are only asking that the agency continue this narrow exemption for retail pharmacy service repackagers for a limited number of drugs.

Rather than having the repackaging occur in hundreds or thousands of different retail pharmacy sites, this "central retail service repackaging" operation helps reduce costs, reduces the potential for pharmacy-based repackaging errors, and reduces the amount of time that the pharmacy needs to be involved in repackaging medications, rather than interacting with and monitoring patients. Labor costs for pharmacies to engage in this type of repackaging at individual pharmacy sites are staggering. However, centralized, off site repackaging reduces costs and increases efficiency at the pharmacy. Workflow efficiency is important in retail pharmacies for many reasons, but it is critical to maintain a safe dispensing process for patients.

An individual pharmacy performing a similar function – that is, dispensing a vial of 100 tablets from a shelf stock bottle of 1000 – would not use its own NDC number, it would use the manufacturers' NDC to accurately describe the product. We see retail service repackagers as performing a similar function – that is, breaking larger stock quantities down into dispensing quantities – only doing it more efficiently, physically away from the actual pharmacy setting.

It has been suggested that retail pharmacy systems might be technologically modified to automatically link repackager NDC numbers to original manufacturer NDC numbers. An analogy has been made to the ability of pharmacy systems to list all different versions of generic drugs in the computer system by simply entering in the generic name of the drug. While conceptually attractive, it is essential to recognize that at this point, there are several technological reasons why this cannot be implemented for retail pharmacy service repackaged drugs. First, each generic company has an assigned NDC code which it maintains, and which is recognized by database companies, software vendors, and third party payers as useable and billable codes for the dispensing of generic drugs. This is not the case with repackaged drugs.

Second, standard codes exist among database companies and software vendors that allow for the listing of all the various generic and branded versions of a multiple source drug through what is known as a "GCN" (Generic Code Number), or a generic sequence number. Thus, as a new generic version comes to market, this new generic not only has its own NDC, but it is also assigned into a GCN that lists all the generic versions together.

When a specific generic version is chosen from among the list by the pharmacist filling the prescription, that specific generic is recognized by the system based on the NDC number for patient safety checks, and is then billed to the third party payer. This NDC number is recognized by database companies, PBMs, insurance companies, Medicaid, and pharmacy software systems.

If retail pharmacy service repackagers are required to use their own NDC numbers on the label, there would be a marked increase in the number of identical products on the market with multiple NDC numbers.

Similarly, use of multiple NDC numbers for repackaged drug products will serve to diminish the potential benefits to patient safety through NDC-based record checks and drug use review operations, such as ensuring against overdosing and underdosing, adverse reactions with other medications, and therapeutic duplications. The existence of multiple NDC numbers for the same manufacturer's product will render it impossible for many pharmacy prescription processing systems to determine that these are all essentially the same product, only repackaged. The process of refilling prescriptions will also be greatly complicated and unnecessary opportunities for confusion may be created. Where a prescription today may be filled with one repackaged product, upon a patient's return, a different repackaged product (or the original manufacturer's product) may be the only item available.

The FDA's proposed change in policy towards NDC numbers will also result in additional complications with respect to adverse event reporting and use of MedWatch by retail pharmacies. Many quality assurance practices that pharmacists rely upon to ensure that prescriptions are filled correctly directly incorporate the use of the NDC number as a validation checkpoint. All of these issues are avoidable consequences of a change in FDA policy that may diminish the potential benefits to patient safety and health care efficiency, and render it more difficult for retail pharmacists to provide better, more efficient care and services to patients.

Modification of the current NDC system will result in added complexity to the drug recall process. In the current environment, the NDC number is the first critical data point that is used in identifying product that is subject to a recall action. This is then followed by a lot number and expiration date. Under the current system, there is a direct one product to one NDC relationship between the recalled product and the NDC that identifies it. Under the proposed changes, this relationship proliferates into a "one product to many NDC ratio." By making the drug recall process more complex, the chances of errors occurring in the process increase correspondingly. The result is a system that is not only less efficient and accurate, but potentially creates a public health risk.

Mandatory use of repackager NDC numbers will also place a significant and unjustified economic burden on retail repackagers due to the Medicaid drug rebate requirements under section 1927 of the Social Security Act. Because state Medicaid payments and calculations are linked to NDC numbers, repackagers would be newly obliged to pay substantial rebate fees, at a statutory minimum of 15.1 percent of original manufacturer sales price. Congress intended drug manufacturers, not retail repackagers, to bear the obligation to pay quarterly rebates on single source and innovator multiple source drugs to the states and the Medicaid program. This fact alone could result in the elimination of repackagers in the marketplace.

It is likely that the change in FDA policy will also create complications in accurate billing, rebate collection and reconciliation for manufacturers, repackagers, state Medicaid programs and the Centers for Medicare and Medicaid Services (CMS). Moreover, because Medicaid drug payments cannot be made without a rebate agreement between manufacturers -- or, under the change in FDA policy, retail repackagers -- and CMS, retail repackagers will either be denied Medicaid payments for their products or simply forced out of this business by economically prohibitive Medicaid rebate obligations. For these reasons, we ask that in the final regulation that the agency continue to allow retail pharmacy service repackagers to place the NDC number of the originator manufacturer on the container, rather than their own NDC number.

Part 207 – Subpart A – General

NACDS supports the exemption of retail pharmacies from the drug registration and listing requirements. Retail pharmacies do not manufacture, repackage or relabel drugs in the context of the definitions proposed by the agency.

Most retail pharmacies also compound some medications for dispensing to patients. The exclusion should be extended to pharmacies that also compound drugs consistent with the practice of pharmacy allowed by the state. This includes the preparation of certain quantities of medication for resale to patients that are made in anticipation of receiving prescriptions for such compounded medications. Most traditional retail pharmacies prepare compounds based on prescriptions that are presented at the pharmacy or in anticipation of prescriptions that will be presented.

In addition, many retail pharmacies purchase and stock drugs that are repackaged for them by another entity. As discussed above in greater detail, retail pharmacies purchase, stock and dispense these repackaged drugs for reasons of efficiency and patient safety. Because these repackaged drugs are dispensed in the regular course of the practice of pharmacy, the proposed rule would also exempt pharmacies that purchase, dispense and stock these drugs from the registration and listing requirements.

NACDS recommends that the definition of repackager be modified such that an entity that repackages drugs for retail pharmacies for the purpose of ultimate dispensing to patients be excluded from the proposed definition of repackager and be defined separately. These entities could put the original manufacturer's NDC on their products rather than their own NDC. This type of repackaging is best described as retail pharmacy service repackaging, and we urge that a separate definition be created and these types of repackagers be allowed to continue to use the originator manufacturer's NDC number on the label. Retail pharmacies purchase these repackaged drugs because the large retail pharmacy service repackager is more efficient than individual retail pharmacies to repackage drugs.

Part 207 - Subpart C – National Drug Code Number

Section 207.33 – Issues Relating to Obtaining and Assigning an NDC Number

Issues Relating to FDA Assignment of the NDC Number

Under the proposed rule, FDA would assign all three sections of the NDC number to drugs that have not been previously assigned NDC numbers by the manufacturer, repackager or relabeler.
This would apparently not apply to NDC numbers that have been assigned to drugs prior to the effective date of the rule. We are supportive of the proposal in the rule that would appear to allow manufacturers to continue to use labeler codes that have been assigned to them, even for new drugs that the manufacturer might bring to market.

NACDS has concerns with the proposal that would require that FDA assign all new NDC numbers for prescription and OTC products after the regulation is made final. We are concerned that the agency may not make such assignments consistent with the logic that has been used by the manufacturer in assigning its own existing NDC numbers. We are also concerned that the agency may not make these assignments in an efficient manner, delaying the release of drugs into the marketplace.

The NDC number is the logical intelligence to a wide variety of systems currently used by the pharmacy distribution system. For that reason, the assignment of a different product and package codes by the agency, even if the labeler code was retained, could create problems for the pharmacy distribution system.

NACDS is also concerned that the proposed rule would require that a manufacturer use only one labeler code if the manufacturer has been using multiple labeler codes. Different "manufacturers" have different subsidiaries that have different labeler codes. If a subsidiary of a manufacturer is using another labeler code, it should be able to continue to use that labeler code and product code to avoid the need to reconfigure pharmacy systems with new labeler and product codes for existing drugs.

We support the requirement that the manufacturer, repackager or relabeler for a private label distributor obtain the NDC numbers from the FDA. Many NACDS members offer private label brands of over the counter products. Under the proposed regulation, these entities – not the private label distributor – are responsibility for registering the drug product and obtaining the NDC number for the private label product.

We also ask that the agency consider whether a manufacturer should be required to make changes to its NDC number for all of the reasons listed in the proposed regulation. For example, we question whether NDC number changes are needed for changes in inactive ingredients. While each change in active ingredient would clearly justify an NDC number change, the number of NDC changes that might be required with each change in inactive ingredient might introduce a significant number of new NDC numbers in the marketplace that would be challenging for pharmacy systems to maintain.

Section 207.37 – Restrictions Pertaining to Use of NDC Numbers

Prohibition on Subsequent Use of NDC Numbers

NACDS supports the proposal in the rule that would require that the NDC number of drug products would change when certain changes are made in the composition of a drug product, such as the active ingredients. We have seen many situations in which a manufacturer has changed the active ingredients or strengths of the ingredients but has neither changed the NDC number nor changed the name of the drug. This leads to problems both in billing correctly for a drug, and in the dispensing of the correct medication.

Specifically, some of these changes have been made by manufacturers for combination DESI drugs or the "brand" version of the DESI drugs combinations when it was just to become subject to generic competition. We agree that the name and NDC number of a marketed prescription drug product should change when active ingredients change.

However, we urge the agency to consider whether the number of potential modifications listed in the proposed rule would all require an NDC number change. While we agree that NDC numbers should identify unique products and packaging, we are concerned that it may be difficult to keep up with all these NDC number changes from a pharmacy operations perspective, and that patient safety implications may also result.

We also believe that requiring all the changes would accelerate the rate at which NDC numbers could be eliminated. For example, should the NDC number be required to change when the manufacturer makes a change in the inactive ingredients of a drug? We urge that the agency consider narrowing this list to only require NDC number changes for changes made by the manufacturer which change the true nature of the drug product or its packaging.

Finally, we urge that the agency consider inventory "sell through" issues when determining the appropriate amount of time to make effective the changes to the labeling of prescription and OTC products. Manufacturers have nine months from the effective date to review and update its information in the FDA system or the agency may assign another NDC code. Prescription products would have to bear NDC numbers 3 years after the effective date and OTC products would have to bear NDC numbers 7 years after the effective date. NACDS urges that the agency consider that not all prescription products are sold through in the market during a 3-year period, and that the 3-year time limit might result in a significant amount of returns by pharmacies to wholesalers. We urge that the agency consider a longer time frame regarding when the NDC number has to appear on prescription containers.

Impact on Medical Devices

In the preamble to the proposed regulation, FDA indicates that some manufacturers have assigned NDC numbers to products that are not drugs, such as "dietary supplements and medical devices; such actions can confuse drug databases or lead to inappropriate reimbursements (see p. 51296)". We have concerns that manufacturers of medical devices – such as diabetic testing supplies – many of which are sold in retail pharmacies – will be unable to continue to use NDC numbers on their product.

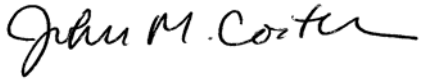
NDC numbers on blood glucose monitoring devices are the key identifier for third-party reimbursement of blood glucose monitoring products throughout the United States. The reimbursement process for blood glucose monitors is identical to prescription drugs. The pharmacy enters the NDC code into their pharmacy system to determine the coverage and co-pay for blood glucose monitors. These systems communicate on-line, real-time to health plan databases, including plans administering Medicaid programs and the new Part D prescription drug benefit. These NDC codes are submitted to multiple data banks (First Data Bank, RedBook, etc.) to make available on their on-line network, which is subscribed to by pharmacies and health plans, again just like prescription drugs.

Further, if FDA requires medical device manufactures to move to a different coding system, every pharmacy computer system, health plan computer system, and related online networks, in use today, would have to be reprogrammed. This would require significant lead time (5 years or greater) as coordination of multiple interested parties would be required.

We urge the agency to reconsider its proposal to restrict the ability of manufacturers of medical devices to use NDC numbers to identify their products.

We appreciate the opportunity to submit these comments and look forward to working with FDA to develop an efficient and credible NDC assignment system that makes the most sense for patient safety.

Sincerely,



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