



Robert P. Giacalone  
Senior Vice President, Regulatory Affairs  
Chief Regulatory Counsel

**Cardinal Health**  
7000 Cardinal Place  
Dublin, Ohio 43017  
614.757.7721 tel  
614.652.4403 fax  
[robert.giacalone@cardinal.com](mailto:robert.giacalone@cardinal.com)

[www.cardinal.com](http://www.cardinal.com)

January 25, 2007

Docket Officer  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20857

**RE: *Docket No. 2005N-0403; RIN No. 0910-AA49* [71 Fed. Reg. 51276, August 29, 2006] 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.**

Dear Sir or Madam:

Cardinal Health ("Cardinal"), the leading provider of products and services supporting the health care industry, submits the following comments regarding the FDA's proposed rule: "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", published in the Federal Register on August 29, 2006, and available at 71 FR 51276. Our comments pertain to the proposed rules affecting the National Drug Code ("NDC") system currently in effect.

#### Assignment of NDCs on Repackaged Drugs

Among Cardinal's many services to the health care industry, we currently provide customers retail service repackaging. Our repackaging division purchases drug products from manufacturers in bulk and repackages them into smaller, more manageable sizes for pharmacy customers. These smaller packages bear the manufacturer's applicable NDC number for that package size. The majority of the savings associated with this bulk purchasing is passed to the pharmacy customer, thereby saving customers money, increasing their inventory efficiencies and eliminating waste.

Repackagers must be registered with FDA and must follow cGMPs, other applicable FDA guidance documents and are subject to FDA inspections and enforcement. Repackagers must also be licensed as distributors under applicable state laws. FDA-registered repackagers provide their own internal tracking code number on the product to identify themselves and to assist in inventory control and product recalls. Adding a unique NDC number would not increase the ability to trace products.

This proposal to require repackagers to place their own NDC number on a product would disrupt this safe, efficient, and cost-effective business. Because the responsibility for the payment of Medicaid rebates follows the NDC on the drug package, repackagers' thin margins associated in

buying products in bulk would quickly disappear<sup>1</sup> and most, if not all, repackagers would likely exit the retail service repackaging industry. This will result in patient safety issues as the repackaging of these products will likely shift from FDA-registered facilities following cGMPS to unregistered pharmacies who do not generally comply with cGMPS.

#### Prohibition Against the Use of NDCs on Non-drug Products

FDA proposal 21 CFR 207.37(d) states that “manufacturers, repackers and relabelers must not use the NDC number on products that are not subject to this part, such as dietary supplements and medical devices.” NDC numbers have been used on devices and other non-drug products for years and have become an integral part of the health care system. The NDC numbers on these products are used to identify co-pays, to process insurance claims, and in ordering and inventory control systems in both the retail and wholesale industry. NDC numbers are also used on non-drug products in patient safety and educational communications. For many of these products, such as certain medical devices and combination products, the reimbursement process is generally identical to that for prescription drugs. A pharmacy uses the NDC numbers on these products to determine coverage and co-pay just as they would for the prescription drug. There are literally hundreds of thousands of these transactions processed per year that depend on the NDC number.

Elimination of the use of NDC numbers on non-drug products would eliminate the existing system of coverage and co-pay, necessitating a higher cost for patients. This proposed prohibition will result in confusion and a disruption in patient access to these devices and other non-drug products. Because NDC numbers are currently printed on product labeling, price lists, contracts, customer support materials, training materials, and sales force materials, a transition to remove this reference number would be extremely costly. Further, pharmacy, health plans and related computer systems would have to be reprogrammed with different identification numbers.

We encourage the FDA to prevent a disruption in patient care and to continue to allow these products to maintain their NDC numbers; at least until a reasonable substitute system for medical devices is available.

#### Private label distributors

Cardinal Health also is concerned with the impact of the proposed rule on private label distributors. Cardinal Health has both private label manufacturing and private label distributing divisions. Under the proposed rule, private label distributors would not be permitted to register, obtain NDC numbers for their drugs, or list those drugs.<sup>2</sup> The ability to self-assign an NDC number is critical for any manufacturer and to a private label distributor as well. Because the private label distributor’s name is on the label, they should bear the responsibility for listing the product and for assigning the NDC number. We encourage FDA to revise the proposed rule to allow private label distributors to register and list products under their labeler code and to self-assign their own NDC number.

---

<sup>1</sup> From the Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement, Section I (1), “‘Manufacturer’ will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.”

<sup>2</sup> Proposed 21 C.F.R. § 207.17(b) (registration); § 207.33(b)(3)(obtaining NDC numbers); § 207.41(c)(drug listing).

Other areas for comment:

We concur with the concerns HDMA raises regarding the proposed definition of the term “relabel” because it would result in redefining as “manufacturing” many common, traditional drug distributor practices. Distributors sticker and tag product to help comply with federal and state requirements and to track, control, and deliver safe, effective drug products to our customers. With changes in state law expected in the next legislative sessions, and many others that have already been enacted, we need the flexibility to be able to respond to new track, trace, and pedigree requirements that states may impose without also triggering FDA listing and registration requirements. We ask that FDA exempt common distributor inventory control, pedigree, track-and-trace, and stickering practices from the definition of “relabel.”

We support FDA’s statement that it intends to maintain the 10-digit NDC number. It would be very burdensome and expensive for us to convert all our systems and practices to a different configuration, such as an 11-digit number. Also, those required to comply with FDA’s bar code rule if the NDC number increased beyond 10 digits.

Lastly, we support FDA’s proposal to transfer the current, cumbersome paper-based establishment registration and drug listing process to an electronic platform. We believe FDA should concentrate its efforts on this aspect of the rule first, and then look at the other issues later after all interested stakeholders have had the opportunity to comment and FDA has had the opportunity to review that testimony.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Giacalone', with a long, sweeping horizontal line extending to the right.

Robert P. Giacalone, R.Ph., J.D.<sup>3</sup>  
Senior Vice President of Regulatory Affairs  
Chief Regulatory Counsel

---

<sup>3</sup> Licensed to practice law and pharmacy in Ohio and Illinois.