

January 25, 2007

Department of Health and Human Services (HHS)
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20851

Re: Docket No. 2005N-0403 and/RIN 0910-AA49 - 21 CFR Parts 20, 201, 207, 314, 330, 514, 515, 601, 607, 610, and 1271 NPRM - *Requirements for Foreign and Domestic Establishment Registration and List for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs* - Comments

To Whom It May Concern:

I am pleased to provide comments on behalf of Wolters Kluwer Health, whose Medi-Span product line supplies NDC-based drug files to pharmacy, hospital, PBM, and insurance partners. We have been in the business of supplying NDC-based drug files since the 1970's and are well aware of the many issues and problems with the current NDC and its use in commerce for the billing and payment of prescription drug claims as well as in pharmacy dispensing applications.

General Comments

We echo the comments of the National Council of Prescription Drug Programs (NCPDP) and applaud the recommendation to disallow the reuse of an NDC number once it is discontinued. Additionally, we also echo NCPDP and highly approve the retention of the basic core NDC enumeration system, the requirement of a new NDC when a physical change is made and when an inactive ingredient change is made.

We applaud the retention of the 10-digit NDC number that can continue to be represented in an 11-digit format that removes the potential for duplication of the true 10-digit NDC across different NDC formats. We also applaud the intent to exhaust all the numeric NDC values before reverting back to an alphanumeric value. We would also recommend not implementing the use of alphanumeric values in the NDC without a lengthy (2-3 years or greater notice), if at all.

We caution that the editorial policy to create a new product code for an NDC (pg. 51302, middle column, 2nd bullet) consider when a strength change will generate a new product code. There are instances where 2 products today may share the same concentration (i.e. 1 mg/1ml), but the products today are considered on the total volume of the product (i.e. 2 ml or 5 ml) and the resulting strengths for the unit are represented as different products. This policy will need to be carefully thought out by the FDA to ensure products are defined consistently.

We agree with the assignment of different NDCs for the unit-of-use blister from the box containing the blisters (pg. 51303, middle column, 1st bullet). We question

though what would be done in the instance of a kit where there are multiple drug products included or drug products and devices. Will the NDCs for the kit components share the same product code or will they same the product code with the drug that is not part of the kit? Likewise, will the NDCs for sample products distributed by physicians also be assigned by the FDA and will their product codes be shared with those who products are dispensed by pharmacies?

As noted in pg. 51305 (bottom of 2nd column), it notes the use of some organizations to label and note their product being represented by an NDC resulting in a misbranded situation. And in the 3rd column, it notes the implementation plan while in the 1st column of pg. 51306, it notes that the FDA will work with manufacturers, repackagers, and relabelers to resolve issues that might arise after a final rule becomes effective. We would recommend that the FDA extend this to the drug database compendia, such as Wolters Kluwer Health - Medi-Span, also. Thus, while the FDA is compiling the official NDC set, they work with the drug database compendia to review what other NDCs have been reported to us so that we can work with the FDA and the manufacturers for another number so that the products are not misbranded with an NDC when they are not eligible for an FDA-approved NDC.

We support different NDCs assigned when a drug product can have multiple manufacturing sites if the active and inactive ingredients, size, shape, color, or imprints change. However, we caution that if this is done as described by one of the participants at the Public Meeting in December and a different number is assigned based on the site and method for the product to be generated when the ingredients, size, shape, color and imprints do not change; this could exhaust the available NDC numbers as well as greatly increase the number of NDCs to manage through the supply chain. We do recommend making the NDCs assigned through the production chain available for products that can be purchased or reimbursed in the supply chain.

Sec. 201.25 Bar code label requirements (pg. 51346)

We agree with NCPDP's response and are very pleased to see that this rule allows for the Bar Code to be continued as part of the label.

Subpart C - National Drug Code Number

Sec. 207.33 What is the National Drug Code (NDC) number, who must obtain it, and what information must be submitted (pg. 51350-51351)

We echo NCPDP and based on the commentary in this section, we agree and applaud this requirement for unique numbers; with the caveat that the FDA assign these numbers in an expeditious manner. Additionally, we would add that these numbers be distributed in an expeditious manner so that drug database compendia can make them available in our drug databases as soon as possible to support the drug dispensing supply chain (ideally, 1 week before the drug is available for ordering and dispensing).

Sec. 207.37 What restrictions pertain to the use of NDC numbers? (pg. 51351)

We echo NCPDP and agree with these requirements.

Subpart E - Electronic Format for Registration and Listing

Sec. 207.61 How is registration and listing information provided to FDA? (pg. 51353)

We echo NCPDP and agree with these requirement for the electronic submission of the NDC.

PART 314 - APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

Sec. 314.81 Other postmarketing reports (pg. 51354)

We echo NCPDP and support this requirement that the list remain current with actively marketed products and would encourage the FDA to use their existing posting processes (listserv) to provide notification of changes to the NDC listing. Additionally, we echo NCPDP and encourage the FDA to apply the same requirement to products listed in Part 330 OVER-THE COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED and to products listed in Part 610 GENERAL BIOLOGICAL PRODUCTS STANDARDS.

Part 330 OVER-THE COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Sec. 330.1 General conditions for general recognition as safe, effective and not misbranded. (pg. 51354)

We echo NCPDP and agree with the listing of these products.

If you have additional questions for how this NPRM will affect drug database compendia, I offer my assistance.

Sincerely,

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