December 6, 2006

Department of Health and Human Services (HHS)
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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 Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs*-Comments

To Whom It May Concern;

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the Establishment Registration and Product Listing for Drugs and Biologics NPRM.

NCPDP General Comments:
NCPDP, according to it's interpretation of the NPRM, applauds the recommendation to disallow reuse of an NDC number once it is discontinued. Additionally, NCPDP highly approves 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. It is our understanding that the NDC will be part of the SPL initiative; as such, the inclusion of the product image from the manufacturer as part of the NDC listing, would further enhance patient safety.

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

NCPDP Response:
NCPDP is 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
Section 207.33 What is the National Drug Code (NDC) number, who must obtain it, and what information must be submitted? (Page 51350-51351)

NCPDP Response:
Based on the commentary in this section, NCPDP agrees and applauds this requirement for unique numbers; with the caveat that the FDA assign these numbers in an expeditious manner.

207.37 What restrictions pertain to the use of NDC numbers? (Page 51351)

NCPDP Response:
NCPDP agrees with these requirements.

Subpart E--Electronic Format for Registration and Listing

207.61 How is registration and listing information provided to FDA? (Page 51353)

NCPDP Response:
NCPDP agrees with these requirements for the electronic submission of the NDC.

PART 314--APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG
Sec. 314.81 Other postmarketing reports. (Page 51354)

NCPDP Response:
NCPDP supports 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, NCPDP encourages the FDA to apply the same requirement to products listed in Part 33Ø 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. (Page 51354)

NCPDP Response:
NCPDP agrees with the listing of these products.

PART 601--LICENSING
Sec. 601.2 Applications for biologics licenses; procedures for filing. (Page 51354)

NCPDP Response:
NCPDP supports 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.

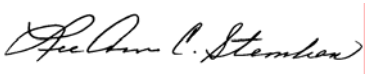
PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS
Sec. 610.60 Container label. (Page 51356)

NCPDP Response:
NCPDP encourages the use of the Bar Code to be used for container labeling.

Sec. 610.61 Package label. (Page 51356)

NCPDP Response:
NCPDP encourages the use of the Bar Code to be used for package labeling.

Sincerely,



Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Dr.
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

cc: NCPDP Board of Trustees
cc: NCPDP Standardization Co-Chairs