March 10, 2020

Lonnie Smith
Office of Health Informatics, Office of Chief Scientist,
Office of Commissioner, Food and Drug Administration,
10903 New Hampshire Ave.
Building 32. Office 2231
Silver Spring, MD 20993-0002
Email: *lonnie.smith@fda.hhs.gov*

RE: Request to add new Structured Product Labeling (SPL) Marketing Category for Outsourcing Facility (OSF) Medications

Dear Mr. Smith:

The National Council for Prescription Drug Programs (NCPDP) submits the following request regarding the addition of a new marketing category specific to OSF Medications to the SPL Sections within the Indexing Structured Product Labeling for Human Prescription Drug and Biological Products.

NCPDP is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 30 years, NCPDP has been committed to furthering the electronic exchange of information among healthcare stakeholders. NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry, as named in the Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing, as named in the Medicare Modernization Act (MMA).

NCPDP supports indexing the content of the SPL as a means to enhance the users' ability to automatically search and sort specific, meaningfully tagged pieces of product information. In addition, key to our commitment to furthering the electronic exchange of information among healthcare stakeholders, NCPDP supports strategic indexing of SPL content that can aid in extracting key elements of data for use in drug compendia content development and maintenance, electronic health records, electronic prescribing systems and a wide array of clinical support systems and tools.

NCPDP respectfully requests the FDA create a new SPL Marketing Category for OSF Medications to eliminate erroneous identification within a database. NCPDP suggests the new SPL Marketing Category be titled "Outsourcing Facility Drugs".

Compounded medications from FDA Registered Outsourcing Facilities are a specific, separately registered category of drugs created by Congress within the Drug Quality and Security Act of 2013. NCPDP members are seeing more medications from OSFs in their trading partners systems. Without a proper SPL home, OSF Medications cannot be

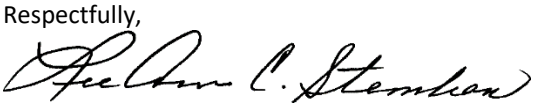
separated from other products without a manual search of the NDC labeler code and subsequent Internet search of the manufacturer associated with such.

As OSF Medications are exempt from the New Drug Application (NDA) pre-market approval process, assigned a manufacturer labeler code and can be adjudicated within the health care system, the proper identification of such products is needed to make quick and meaningful identification decisions utilizing automated systems and databases in a seamless fashion.

Better identification of SPL is important because currently drugs compounded at Outsourcing Facilities are listed as "unapproved drug, other", which contains DESI drugs from the 1950s, convenience kits and a variety of other medications. OSF Medications are not a product of the 1950s, but rather the new millennium; they are sanctioned by Congress, and the only drug products that are statutorially declared exempt from the pre-market drug approval process. The lack of a category for clinically needed medications for hospitals, physicians, pharmacies and patients is creating confusion not only within the medical community among healthcare providers, but also with payer systems and software logic which could potentially create a decision of non-coverage.

Therefore, NCPDP is requesting the FDA create a new SPL Marketing Category for OSF Medications to eliminate erroneous identification and help in the proper identification of OSF compounded medications. As there are already SPL marketing categories for NDA, ANDA, Medical Devices, etc., and with the provisions created by Congress within the Drug Quality and Security Act of 2013, the creation of the requested new SPL Marketing Category Code is necessary and appropriate.

Respectfully,



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