June 29, 2021

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

Re: Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices

Dear Ms. Stember:

Thank you for your June 4, 2021, letter regarding FDA's guidance, *Enforcement Policy Regarding Use of National Health Related Item Code and National Drug Code Numbers on Device Labels and Packages*,[1] issued on May 21, 2021.

We appreciate the concerns raised in your letter regarding stakeholders' readiness for use of the unique device identification system (UDI system). This guidance update was informed by the helpful input from stakeholders, many beyond the direct regulatory reach of the unique device identifier (UDI) regulations, regarding the continuing need to transition beyond legacy FDA identification numbers.

During the phased implementation of the UDI system, FDA has regularly engaged with members of the device industry on implementation of UDI requirements, as well as with other stakeholders, to encourage the adoption of UDI across the U.S. healthcare system. FDA is aware of the readiness concerns that NCPDP and other stakeholders have raised and, as indicated in the guidance, believes limited additional time to complete the activities needed to transition systems away from use of legacy FDA identification numbers is appropriate and in the interest of public health.

We welcome the opportunity to meet with you to discuss your information and perspective regarding the time needed to transition to use of UDI. Please contact Dr. Michelle Tarver to schedule a meeting with the appropriate persons.

[1] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-regarding-use-national-health-related-item-code-and-national-drug-code-numbers.

Thank you for your commitment to work together to encourage the adoption of UDI.

Sincerely,

Suzanne B. Schwartz -S

Digitally signed by Suzanne B. Schwartz -S
Date: 2021.06.29 13:40:07 -04'00'

Suzanne B. Schwartz, MD., MBA
Director - Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health
Food and Drug Administration

Cc: Sandra Garnand
Standards Specialist, Standards Development
NCPDP
standards@ncpdp.org

Paul Loebach
Branch Chief – Drug Registration and Labeling Branch
CDER
Paul.loebach@fda.hhs.gov

Michelle Tarver, MD, PhD
Deputy Director - Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health
Food and Drug Administration
Michelle.Tarver@fda.hhs.gov