June 12, 2020

Hunter Gordy
Vice President of National Accounts
Nephron Pharmaceuticals Corporation
4500 12th Street Extension
West Columbia, SC 29172
Sent via-electronic mail

Subject: Reuse of National Drug Code (NDC)

Dear Mr. Gordy,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, 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.

It has come to the attention of NCPDP that Nephron Pharmaceuticals Corporation has reused the NDC for a product having different quantities:

- NDC 00487-9003-60 was previously marketed as Sodium Chloride Inhalation Solution 3% 30 x 4mL and is now marketed as Sodium Chloride Inhalation Solution 3% 60 x 4mL.

NCPDP is strongly opposed to the reuse of the NDC for different quantities and respectfully requests that you cease this practice for the reasons detailed below.

Effective April 1, 2019, the Code of Federal Regulation (Section 207.35) states:

§207.35 What changes require a new NDC?

(a) Once an NDC has been assigned by FDA, the registrant must propose a new and unique NDC for a drug when there is a change, after the drug is initially marketed, to any of the information identified in paragraphs (b) and (c) of this section. A new NDC must be proposed to FDA for assignment through an updated listing in accordance with 207.57.

(b) The proposed new NDC must include a new product code when there is a change to any of the following information:

(1) The drug's established name or proprietary name, if any;

(2) Any active pharmaceutical ingredient or the strength of any active pharmaceutical ingredient;

(3) The dosage form;

(4) A change in the drug's status, between prescription and nonprescription, or for animal drugs, between prescription, nonprescription, or veterinary feed directive (VFD) status;

(5) A change in the drug's intended use between human and animal; or

(6) The drug's distinguishing characteristics such as size, shape, color, code imprint, flavor, and scoring (if any).

(c) When there is a change only to the package size or type, including the immediate unit-of-use container, if any, the proposed new NDC must include only a new package code and retain the existing product code unless all available package codes have already been combined with the existing product code in NDCs assigned by FDA.

The NCPDP Product Identifiers Standard Implementation Guide was developed at the behest of FDA to define, clarify and ensure continuity of the Product Identification Codes for drugs and other items used in the healthcare marketplace. According to Sections 4.3 and 4.4.c of the Product Identifiers Standard v1.4:

"Identifiers are to never be reused. Once assigned to a product based on the chemical, strength (if applicable), dosage form (if applicable), route of administration (if applicable) and package size, the identifier should never be assigned again".

"A new identifier will be assigned if any of the following characteristics of the product/package change:

a. *Product name change*
b. *Active ingredient change including use of a different salt*
c. *Package size change…."*

NCPDP's primary concern is patient safety and reuse of the NDC can result in medication dispensing errors. Pharmacy automation, workflow and processing systems are often designed to base product selection on the NDC. The NDC is commonly used as a unique identifier to ensure the correct medication is dispensed at the point of care. This verification can be manual or electronic. Without assurance that two products will never have the same NDC, medication errors may result.

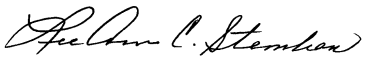
In addition, the reuse of an NDC can lead to undue administrative cost and billing errors. The NDC is used for benefit design set-up, rebates, and for MAC/FUL price mapping. The reuse of an NDC could result in a payer remitting for a product which should not be covered, not paying for a product that should be covered or it may result in an incorrect reimbursement.

NCPDP shares with you the common industry objective of medication dispensing safety and to that end thank you for consideration of its request.

For direct inquiries or questions related to this letter, please contact

Terry Fortin
Assistant Senior Manager
NCPDP
Direct: 480-297-4593
standards@ncpdp.org

Respectfully,



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

cc: NCPDP Board of Trustees