AMSINO
Advancing Healthcare Worldwide®

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MEMO

From: Cathi Dykes, Director of Quality

Date: May 11, 2022

Re: NDC Codes for Amsino Medical Device Products

On September 24, 2013, the Food and Drug Administration (FDA) issued a Final Rule for unique device identification (UDI). The rule is phased in over a seven-year period to allow companies to make necessary changes for compliance.

21 CFR 801.57 (Discontinuation of legacy FDA identification numbers assigned to devices) states:

> *(a) On the date your device must bear a unique device identifier (UDI) on its label, any National Health-Related Item Code (NHRIC) or National Drug Code (NDC) number assigned to that device is rescinded, and you may no longer provide an NHRIC or NDC number on the label of your device or on any device package.*

Several Amsino products that are classified as medical devices, and thus included in the regulations. As a result, Amsino is prohibited from labeling our medical device products with an NDC code.

We understand that this has created industry-wide billing concerns while companies determine how to sort and bill for these products. The FDA issued a guidance document on this topic that can be viewed at fda.gov. If you have any questions, please don't hesitate to contact me.

Thank you,

C. Dykes 11May2022

Cathi Dykes
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