January 2, 2018

From: Pharma & Biopharma Outsourcing Association
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Tel: 201-788-7994

To: Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments from Pharma & Biopharma Outsourcing Association (PBOA) on Docket No. FDA-2018-N-2610 for "*Future Format of the National Drug Code*".

Dear Sir or Madam,

On behalf of the Pharma & Biopharma Outsourcing Association ("PBOA"), a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations ("CDMOs"), I am pleased to offer feedback on the recent draft guidance, "*Future Format of the National Drug Code; Public Hearing; Request for Comments*". Our Serialization Working Group, composed of serialization leads from more than a dozen of our member companies, has discussed this draft guidance and outlined concerns on issues that we believe will negatively impact the industry and our ability to meet the requirements of the Drug Supply Chain Security Act (DSCSA).

Changing the NDC format from ten digits to eleven digits has implications that justify consideration of alternate solutions to the need for unique labeler codes.

- The Product Identifier (PI) draft guidance (docket FDA-2018-D-3175) states "The term 'standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code. . . . " Due to the lack of prior FDA guidance, industry has adopted the GS1 standards for Global Trade Identifier Number (GTIN) as the Product Identifier (PI) because a serialized GTIN uniquely identifies a product, aligns with the standards of an international standard-setting body, and enables electronic interoperability and data exchange as required by DSCSA. The preponderance of feedback from industry on this docket requests the FDA adopt the GTIN as the PI. The GTIN system is built on and incorporates the 10-digit NDC code. Expanding the NDC to twelve digits will necessitate expansion of the GTINs accordingly.
- Also as part of this guidance, if the FDA elects to require both the GTIN and NDC included in the human readable portion of the label, there may be difficulty fitting all this information on the label. Some Marketing Authorization Holders (MAHs) appear to be considering removing the GTIN to allow room for the NDC, which will raise issues with DSCSA compliance. The purpose of the human-readable portion of the PI is to display the exact

data within the barcode, in case the barcode becomes damaged and unreadable. If the NDC is added or GTIN is removed, this will cause confusion in product verification activities and could lead to false suspect product investigations.

- Changing the NDC to an eleven- or twelve-digit format will require the NDC to become an attribute of the GTIN, which will require an additional field to be printed. The field does not presently exist, though GS1 has attributed the 7xx range to it (next one in the series is 715), which could become the US National Health Number. The existing guidance on the human-readable portion of labels cannot accommodate these new requirements. Some of our members have reported customers filing labels that do not appear compliant, but have received approval.
- In addition, all existing NDCs would need to be converted to the new format, presumably by introducing leading zeros. This will require a good deal of effort and paperwork, without obvious benefit. We recommend that FDA consider making NDCs alphanumeric, which would open the current format to near limitless unique identifiers, resolving the current issues and maintaining the ten-digit structure.

PBOA appreciates the opportunity to review and provide comments pertaining to the draft guidance. We look forward to working with FDA on its continued efforts to implement the DSCSA while adapting to the growth of the industry.

Thank you for considering our views.

Respectfully,

Christopher Verbicky

Chris Verbicky, Ph.D., M.B.A.
Director, Scientific and Regulatory Affairs
PBOA

PBOA Member Companies

3M Drug Delivery Systems
Ajinomoto Bio•Pharma Services
Alcami
Avid Bioservices
Avista Pharma Solutions
Afton Scientific
Baxter BioPharma Solutions
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CMIC CMO USA, Inc.
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DPT, a Mylan Co.
Grand River Aseptic Manufacturing
Groupe PARIMA
iBio Inc.
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