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BY ELECTRONIC FILING

Paul Loebach,
Director, Drug Registration and Listing Staff
Center for Drug Evaluation and Research
Food and Drug Administration
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Dear Mr. Loebach:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide input to the Agency in response to its notification that FDA must consider the Future Format of the National Drug Code (NDC). Dkt. No. FDA-2018-N-2610, [83 Fed. Reg. 38666 (Aug. 7, 2018)].

HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA appreciates that the finite number of labeler codes available means that the Agency will eventually “run out of” NDC numbers. Thus, we applaud the Agency’s early steps to seek solutions, for taking them well in advance of the point at which a conversion must be made, and for seeking input from, and remaining sensitive to, the public’s needs and recommendations.

To help understand the wholesale distribution industry’s own usage of the NDC, HDA and its members have begun the arduous task of inventorying the many multiple internal databases and tracking systems used by HDA’s members. These databases and systems employ the NDC for identification purposes and support management of the drug products that eventually reach dispensers to meet their patient care needs. Such databases and systems include, but are not limited to:
• Product ordering, including wholesale distributor purchases from manufacturers and
dispenser purchases from wholesale distributors,
• Inventory tracking,
• Tax and other financial recordkeeping,
• Rebates and chargebacks,
• Regulatory reporting (e.g., the Drug Enforcement Administration (DEA) and other federal
and state regulatory bodies),
• Reimbursement, and
• Receiving, shipping, and associated Electronic Data Interchange\(^1\) (EDI)
interfaces/transactions.

An inventory of such databases, systems and reporting requirements will aid us in developing
additional recommendations for the Agency as they consider a new form and format.

HDA was also pleased to be able to attend the public meeting held on November 5 and has been in
consultation with our members about the discussions held there. We found it helpful to understand
insights and challenges among others in the supply chain. We also fully agree with speakers who
urged FDA – as long as the NDC format must change – to comprehensively overhaul how drugs, and
indeed all medical products, are identified. We urge the Agency to devise a solution that will serve
the U.S. pharmaceutical and medical product supply chain for well into the future.

At the current time, HDA is evaluating the formatting Options FDA has proposed, as well as
additional options under consideration by several standard-setting organizations and others, including
those who provided input at the public meeting.

Based on the information presented at the meeting, and additional discussions with our members,
HDA offers the following initial input for FDA’s consideration. These points reflect the fact that
implementation will involve not only a decision on the actual form and format, but also of when and
how the transition takes place.

1. Options for the NDC’s form and format

FDA’s website outlined four options: Options A, B, C and D, and other speakers at the public meeting
provided at least one more for consideration.\(^2\) HDA is still evaluating the options and does not yet
recommend a specific format. However, we note our agreement with those speaking at the public
meeting that FDA’s first three Options, A, B and C, are infeasible. Some of them, for example, would
negatively impact bar code technology and interoperability, and others would perpetuate, or even

\(^1\) Electronic Data Interchange (EDI) is commonly defined as the transfer of structured data (by agreed message
standards) from one computer system to another without human intervention. EDI is the data format used for the
vast majority of electronic commerce transactions in the world. Once the EDI information is sent, back-end systems
convert the data through a translator into a single format for use by the receiver.

\(^2\) FDA’s proposed options and the Webcast presentations, including an additional option, can be viewed on FDA’s
website located [here](#).
exacerbate the confusion created by the current multiple formats, by adding even more formats. These three Options could also result in creating duplicate NDCs.

HDA is also participating in discussions taking place within GS1, an internationally recognized standard-setting body. GS1 is currently considering two options, the first of which would be FDA’s Option D. The second is a potential standards-based option, essentially a recommendation to employ the Global Trade Identification Number – or GTIN – which is a type of numerical identifier that currently incorporates the NDC.

As noted earlier, HDA does not, at this stage, recommend any specific option, and if the standards-based option is selected, we anticipate that the GTIN would replace, and become, the NDC. Thus, we strongly encourage FDA and other affected stakeholders to “think outside the box” and to do so by allowing consideration of an even more comprehensive change than merely adding digits to the current NDC’s form. As HDA further considers these and other options, we will provide additional input and recommendations to the Agency.

2. Inter- and Intra-Agency coordination to achieve a single unchangeable NDC format

HDA cannot emphasize strongly enough that it is imperative for CDER to closely coordinate its NDC efforts with other numerical identification efforts ongoing throughout the Agency. Key among them are the Center for Devices and Radiological Health’s (CDRH) work on the Unique Device Identifier (UDI) and CDER’s oversight and implementation of the Drug Supply Chain Security Act’s (DSCSA) requirements for a Product Identifier.4

We also urge FDA to closely coordinate with, and involve in its conversion discussions, other regulatory bodies at both the federal and state level. These include, but are not limited to, the Centers for Medicare and Medicaid Services (CMS), which uses the NDC to help identify appropriate reimbursement values, the Drug Enforcement Administration (DEA) which uses NDCs to help identify opioid products listed within its systems and for such regulatory actions as DEA-determined scheduling decisions and, possibly, by such state regulatory authorities as the Boards of Pharmacy (BOPs). These entities likewise maintain internal systems and databases that use the NDC, and/or have reporting requirements for regulated entities to submit data which includes the NDC.

In the past, non-FDA regulatory authorities have established requirements to add to, or modify, the NDC to facilitate certain agency-specific requirements. However, we strongly believe and encourage FDA, as the best course of action to:

- reduce the opportunities for errors and confusion and help make the transition as smooth as possible, by establishing a single, unchangeable format for all purposes, uses, and regulatory authority applications of the NDC,

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3 See: https://www.gs1us.org/ for more information on GS1.
4 See: DSCSA § 581(14).
• encourage the involvement of these additional regulatory bodies and stakeholders early on, to ensure the new format meets their needs as well as that of FDA and of the pharmaceutical supply chain, and

• ensure comprehensive notification to all affected parties, including federal and state regulatory authorities, as well as to supply chain members, well in advance of the format change, and allow ample time for these entities to make the system changes that the new format will effectively require.

We hope that by doing so, we would avoid the disorder resulting from the current situation where multiple formats of the NDC are employed, or complex conversion algorithms are necessary, to sort out the confusion.

3. Transition lead time considerations

HDA strongly agrees with participants at the public meeting on the need for a considerably long lead time between the final decision on the new NDC form/format and the effective date for its implementation. Until we know the exact format the NDC will take, and can begin to assess the conversion challenges, it is difficult to accurately gauge what would be an adequate amount of lead time for the conversion. However, our current view is that the 10-years after a final format is established, recommended at the public meeting, is likely appropriate. If anything, 10 years may even be too short for some, particularly the small businesses among the supply chain.

We believe that a 10-year lead time frame is needed under the best of circumstances. However, it is not just recommended but imperative, for the Agency to recognize the unique challenges that the conversion poses given that November 27, 2023 is also the statutory deadline for meeting the DSCSA’s end point requirements for full traceability.5

As of that date, all covered transactions must include, with the Transaction Information (TI) data that they provide to the next owner, the DSCSA-mandated serialized product identifier. Building the methods to transmit such data is a time-consuming task that trading partners have already begun to plan, as accurate transmission requires a multi-year effort to design, test, revise, and install on a large-scale basis for the literally tens of thousands of products that are shipped each day and subject to DSCSA-requirements.

Avoiding a “cut over” date that is before, during or even shortly after the 2023 DSCSA deadline, will also help avoid the all but certainty that distribution systems will encounter significant safety and security challenges posed by two concurrent major systems changes. Meeting the DSCSA deadline, alone, will involve major business, staff and financial challenges. Additionally, the same employees knowledgeable in their company’s systems and have the IT expertise to meet the DSCSA requirements would be relied upon for implementing the NDC change-over, effectively expecting them to do “double duty” to meet both sets of requirements simultaneously.

5 See: DSCSA § 582(g).
Layering a revised NDC format change over the DSCSA’s 2023 deadline will pose a tremendous – if not outright impossible – challenge, at least if both are to be accomplished with the surety of data accuracy, and without affecting product availability. Each of these requirements, alone, will involve complex IT systems design, testing, revisions based on test results, and likely more testing, (before and after installation). Moreover, after the DSCSA’s deadline, there will be several years of corrections, ironing out the “bugs,” modifications to accommodate customer/supplier mergers and acquisitions, and/or modifications due to the sheer volume of transactions that simply cannot be tested before the “goes live” date for all transactions. Even if financial resources allowed for extensively expanding the workforce (and the financial challenges will be considerable without staff increases) it takes years for an employee to come up to speed on a company’s systems. New staff could not do so rapidly enough to enable a concurrent change.6

Moreover, additional business considerations should play a role in the conversion timeline. For example, the NDC change may result in unexpected challenges in obtaining appropriate reimbursement, could affect how accountability for product ownership is determined after mergers and acquisitions, and/or placement on state Medicaid or individual insurance formularies. It will take years of preparation to address and hopefully prevent, these or other potential “glitches”.

Thus, we urge that the Agency establish a multi-year lead time for the conversion to help avoid, as much as possible, the negative consequences if the supply chain is unable to provide patients with the products they need.

4. Single “Cut over” date vs. “rolling” transition

Several speakers at the public meeting suggested that FDA establish a single date that represents a firm, absolute, single deadline to “cut over” to use of the new NDC. HDA agrees that a single “cut over” date is appropriate. For wholesale distributors, similar to dispensers and others in the supply chain, a firm, specific date is important for planning, budgeting, and conversion management reasons.

However, we wish to clarify what we envision a “cut over” date means. Specifically, we believe that this would be the date on which all Federal (and, hopefully, state) agencies would convert to the new format. If the 6-4-2 format is selected, for example, industry would change its systems such that as of that day, they would put a leading zero in the short segment and then add a leading zero to the front of the NDC for any current 10-digit NDC. They would use the 6-4-2 digit format when electronically communicating with a Federal Agency such as when making requests for reimbursement from CMS, or when notifying FDA of an illegitimate product by way of FDA’s Form 3911, or when submitting

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6 HDA adds that the DSCSA’s requirements for providing data and other obligations have sometimes proven to be extremely complex. So much so that stakeholders have sometimes requested, and FDA has granted, enforcement discretion to effectively allow these entities much needed additional time to comply to avoid disrupting the supply of drug products. Should the supply chain need additional time to meet the DSCSA’s 2023 requirements, a comparable extension of the NDC format conversion time frame, potentially beyond the recommended ten-years, may need to be similarly considered.
Automation of Reports and Consolidated Orders System (ARCOS)\(^7\) data to DEA. Also, FDA would begin to assign only 12-digit NDCs from that day on.

However, for a time, there will be a certain amount of “hold over” to the old format. For example,

- Physical products already in wholesale distributor or pharmacy inventories will retain the 10-digit NDCs on the products’ outside labels and package inserts,
- Initially, most product returns will exhibit the 10-digit NDCs on their outside containers for several years while inventories gradually turn over,
- The DSCSA-required Product Identifier, which includes the NDC, will remain on the physical containers to which they were affixed for products already in inventory,
- Companies will need to evaluate their inventory tracking systems, product ordering or other business systems that make use of an NDC to determine when to “cut over” such systems to the new NDC format. They should have the flexibility to continue using the old format for their product monitoring and other non-FDA regulated uses as long as it is necessary, and,
- There may be other instances where both formats would coexist for a period of time.

It is also important to establish the “rules” for the change-over as soon as possible so that design, testing, and follow-up modifications to the design after testing can be made before the official “cut over” date. This includes establishing the exact – and final – format long before the conversion must take place.

5. **Enhance the NDC**

One speaker at the public meeting suggested that FDA “enhance” the NDC to include an indicator of such information as the product’s hazard class or whether it is a DEA-regulated opioid. HDA cannot agree with this suggestion. Inclusion of *any* additional “smart” data/digits will

- Result in significant delays in the conversion because before adding such digits/information, a new standard to ensure consistency in usage will be needed, likely requiring months, if not years, to develop,
- Additional digits will open the potential for additional errors, if only because there are now more of them to enter in/code,
- As made clear at the public meeting, with so many products now available, pharmacists are no longer able to identify an individual product merely by looking at an NDC. Additional data/digits will only make it less likely they can identify individual products, not better identify them.

Thus, the added-value of more digits/information from a product safety perspective is likely nonexistent and may even be detrimental if it adds more confusion about the NDC’s meaning or detracts from identifying the product. We emphatically reject the concept of including additional digits that go beyond a baseline or a statutorily-defined convention.

\(^7\) See: the [DEA website](https://www.deadiversion.usdoj.gov) for an ARCOS reporting requirement description.
6. Additional considerations

HDA’s wholesale distributor members, uniquely positioned in the middle of the supply chain because they both purchase and sell NDC-coded products, and which are implementing the DSCSA, offer the following additional suggestions that we hope will help inform FDA’s NDC conversion efforts:

a. Several dispenser organizations recommended that FDA not establish January 1 as the “cut over” date because many other system changes become effective on the first of the year. HDA agrees that a January 1 “cut over” date poses unique challenges. Many systems throughout the supply chain, including some that are not specific to safety or security but are nevertheless very important, undergo changes as of that date, (e.g., accounting for tax purposes, company fiscal year budgets which start on the first of the year, etc.). Further, individual companies face separate, resource-intensive business obligations that often take place at the end of the calendar year that consume resources (e.g., state and local license/permitting renewal requirements at a time when issuing authority employees are less accessible due to holiday leave schedules). These obligations can result in a different, but nevertheless impactful, type of year-end time challenge. HDA also suggests that avoiding a date at the beginning or end of a quarter (e.g., April 1, July 1, October 1), while not as impactful as a January 1 date, would also pose substantial challenges. If a single start date is contemplated, HDA recommends that the Agency select a date at least one month after those listed above.

b. We have seen that even five years after enactment, many dispensers remain unaware of the DSCSA’s existence, much less their responsibilities under this important statute. Based on this experience, we believe it is likely that dispensers will be similarly unaware of the NDC change. Thus, we cannot urge FDA strong enough to seek methods and forums for educating them, particularly smaller dispensers, on the upcoming change and what it will mean.

c. We also urge FDA to consider the states’ usage of the NDC, including:
   - Assess how the NDC change will impact the states (e.g., how do states use the NDC for Medicaid reimbursement? What other state systems/reporting requirements are impacted?),
   - Identify methods and forums for educating the states, and
   - Prepare recommendations to the states on identifying budgetary needs, amending their own systems, and possibly their legislation, regulations or reporting forms, to accommodate a new NDC format.

d. We recommend that FDA catalogue the Agency’s own guidances, regulations, reporting forms or other documents that would need to be modified to match up with a new NDC format. (e.g., annual reporting by manufacturers and repackagers; illegitimate product notifications on Form 3911). It is possible that once the Agency identifies the number and complexity of their own internal systems, and goes through the notice and comment processes that may be needed to revise certain forms and other information, FDA may also need at least a 10-year lead timeframe to transition all of its own systems, information databases, etc.
HDA concludes by reiterating its appreciation for this opportunity to provide input on the Agency’s plans for amending the NDC and for recognizing the NDC’s extensive use and the enormity of the conversion process that will have to be undertaken. We support these efforts to derive a new format that will, as much as possible, avoid disruption; support a safe, secure drug supply; contain costs and enable a transition that is as error-free as possible as we continue to provide drug products to the patients who need them.

If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs