

February 13, 2026

The Honorable Russell T. Vought  
Director  
Office of Management and Budget  
725 17th St. NW  
Washington, DC 20503

The Honorable Marty Makary  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

The Honorable Robert Kennedy, Jr.  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Vince Haley  
Director  
Domestic Policy Council  
Eisenhower Executive Office Building  
1650 17th Street, NW  
Washington, DC 20500

Dear Director Vought, Secretary Kennedy, Commissioner Makary, and Director Haley:

The undersigned organizations representing the full breadth of the U.S. health care system write to urge prompt finalization and publication of FDA's Rule, *Revising the National Drug Code Format and Drug Label Barcode Requirements* (Docket No. FDA-2021-N-1351; RIN 0910-AI52) (the "NDC Format Rule"). FDA is nearing depletion of National Drug Codes (NDCs) in the current NDC format, and the NDC Format Rule will establish a new NDC format to allow the continued issuance of NDCs. **The NDC Format Rule is an operational necessity for the continued functioning of the health care system. Further delay in its release will add complexity and cost to its implementation and jeopardize patient care.**

The NDC is a 10-digit code used to identify all prescription drugs, over-the-counter drugs, and animal drugs. The NDC is utilized by virtually every system in health care, including manufacturing, customs, distribution, pharmacy operations, prescribing, care delivery, billing and reimbursement, safety monitoring and reporting, and more. In all, more than 100 different public and private systems across the health care ecosystem rely on the NDC.<sup>1</sup> FDA expects to exhaust its current inventory of 10-digit NDCs as soon as 2032. If the new format, and system updates to handle that new format, are not in place and operational across all systems by that date, the delivery of drugs to patients will be severely disrupted. The new NDC format to be established by the NDC Format Rule is therefore necessary<sup>2</sup> for the continued issuance of NDCs and the smooth operation of the health care system.

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<sup>1</sup> GS1 US, Appendix C, Comment to the United States Department Food & Drug Administration regarding: *Revising the National Drug Code Format and Drug Label Barcode Requirements* Docket No. U.S. FDA-2021-N-1351, available at [https://downloads.regulations.gov/FDA-2021-N-1351-0036/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2021-N-1351-0036/attachment_1.pdf) (last accessed Dec. 15, 2025).

<sup>2</sup> In fact, the NDC Format Rule can in many ways be viewed as a deregulatory action. The current 10-digit format uses a variable structure, which adds complexity to various systems. The NDC Format Rule will unify the industry behind a single structure. It will also add greater flexibility to the current barcoding requirements associated with the NDC under 21 CFR § 201.25.

Implementation of the new NDC format to be announced in the NDC Format Rule will require coordinated updates to virtually every public and private system that incorporates or relies on drug-related data—systems that impact nearly every part of the health care ecosystem and are critical to large and small business operations and patient care. The upgrades will be complex and time-consuming and must be coordinated among thousands of organizations across disparate parts of the health care ecosystem that do not have well-established operational working relationships, increasing implementation risks. Implementation extends far beyond simply updating the NDC number affixed to a given drug package. Downstream systems that facilitate distribution, prescribing, administration, and payment for those drugs must all be updated—in a coordinated manner—to accommodate the new format without disrupting access to drugs distributed under the current format.

Planning, implementation, and testing of the necessary system updates will take years but cannot begin until the final requirements of the NDC Format Rule are known. FDA issued the Proposed Rule in 2022 with a proposed five-year implementation period to accommodate the necessary system updates. Many comments to the Proposed Rule expressed concern that the five-year implementation period may be too short to facilitate orderly implementation, but with the continued delay of finalization, even that five-year period is at risk given FDA may exhaust its current inventory of labeler codes by 2032. With each passing week, the implementation window gets shorter. The compressed implementation timeline will only make implementation more difficult and more expensive for the health care system and create greater risk to patient access.

**The NDC Format Rule is an operational necessity across the health care ecosystem. We strongly urge FDA and OMB to finalize and publish the NDC Format Rule expeditiously and no later than March 31, 2026.**

Sincerely,

AbbVie  
American Pharmacists Association  
American Society of Health-System Pharmacists (ASHP)  
Antares Vision Group  
Apotex Corp  
Association for Accessible Medicines (AAM)  
athenahealth  
Ballad Health  
Cencora  
Consumer Healthcare Products Association (CHPA)  
Essentra Pharmacy  
Federation of American Hospitals  
Geisinger  
GoodRx  
GSK

GS1 Healthcare US  
Harmony Biosciences  
Healthcare Distribution Alliance  
Hercules Pharmaceuticals  
Henry Ford Health  
Inmar Intelligence  
National Association of Chain Drug Stores  
National Association of Specialty Pharmacy  
National Community Pharmacists Association  
National Council for Prescription Drug Programs (NCPDP)  
Novartis Pharmaceuticals  
Oracle Health  
Pharmaceutical Research and Manufacturers of America (PhRMA)  
RxEOB  
RxLogic  
RxScan  
RxWallet  
Sam's Health Mart Pharmacies  
Systech  
Uptown Pharmacy  
Value Drug Company  
Viatris  
Vizient, Inc.  
Wolters Kluwer