January 5, 2026

Tracey Beth Høeg, M.D.
Director, Center for Drug Evaluation and Research
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Gerald Dal Pan, M.D.
Director, Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Leyla Rahjou-Esfandiary, PharmD
Branch Chief
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Request to Revise 21 CFR 201.25(c)(1) – Bar Code Requirements on Immediate Prescription Drug Containers

Dear Drs. Høeg, Dal Pan and Rahjou-Esfandiary,

The undersigned professional organizations and industry representatives respectfully urge the FDA to revisit and revise the 2004 Drug Bar Code Label Requirements [21 CFR 201.25(c)(1)].

Specifically, we request that the FDA mandate the inclusion of lot numbers and expiration dates—along with the currently required National Drug Code numbers (NDC)—in bar codes on all immediate prescription drug containers.

The original intent of the 2004 Rule was to include lot numbers and expiration dates along with NDC numbers in bar codes on all immediate prescription containers.[1] However, machine-readable symbologies and scanning technologies at that time required one-dimensional bar codes, incapable of containing data beyond NDC numbers. Today, two-dimensional symbologies and modern scanners easily accommodate and accurately read this additional, critical data.

The 2013 Drug Supply Chain Security Act (DSCSA) acknowledges technology's readiness for our request by requiring 2D bar codes containing the NDC, lot number, expiration date, and serial

[1] We have included public comments received and FDA responses to the inclusion of the lot number and expiration date in the initial bar code regulations (see attachment).

number[2] on "each package and homogenous case." However, this requirement only extends to the *lowest saleable unit*. It does *not* apply to immediate containers used for preparing or administering medications. FDA regulation continues to require that immediate prescription containers be labeled with old linear barcodes.

Amending 21 CFR 201.25(c)(1) to require 2D bar codes with the NDC, *lot number, and expiration date* on all immediate prescription containers would facilitate:

- Enabling consistent and efficient identification and removal of outdated and recalled drug products from inventory
- Decreasing medication errors and adverse events from expired and recalled drugs
- Improving inventory management to avoid drug shortages
- Ensuring critical lot and expiration data are documented efficiently, consistently, and accurately as required by rules, laws, and codes

Fortunately, a proposed FDA initiative already exists to help facilitate the addition of lot number and expiration date on immediate prescription drug containers. In July 2022, the FDA issued a draft rule proposing to expand the format of the NDC from 10 to 12 digits and amend 21 CFR 201.25 to allow the use of nonlinear barcodes (FDA-2021-N-1351). As of this writing, this rule has not been finalized.

The proposed change to the NDC format is driven by the dwindling inventory of 10-digit NDCs available for new FDA-approved drugs. As such, FDA and industry need to transition to an expanded format. By also allowing the use of nonlinear barcodes to enable that transition, FDA is creating the opportunity to add other vital drug safety information on immediate medical containers. Industry will already be incurring significant costs to implement new systems to accommodate the expanded NDC format. Also, requiring lot number and expiration date would not impose added burden and could help save lives.

We realize FDA's July 2022 draft rule did not propose to include lot number and expiration date in its proposed amendment to the barcode requirements, and that such changes will need to be formally proposed by the Agency and subject to public comments. FDA anticipates a transition period of at least 5 years for industry to adopt the new NDC format, more than sufficient time for the Agency to propose this additional amendment to the barcode requirements.

To safeguard America's patients, we therefore urge the FDA to revise 21 CFR 201.25(c)(1) to read that the bar code on each immediate prescription container:

> "...contains, at a minimum, the appropriate National Drug Code (NDC) number, Lot Number, and Expiration Date in a 2-dimensional Data Matrix barcode, which can be verified using human-readable and machine-readable methods and conforms to standards developed by a widely recognized international standards development organization."[3]

---

[2] We are NOT asking that bar codes on immediate drug containers include serial numbers.

[3] Changing the current format and content of the linear bar code requirements at 21 CFR 201.25 (c)(1) with the format and content (minus serialization) currently required under section 582 of the FD&C Act as added by the Drug Supply Chain Security Act (DSCSA)

For your reference, we have included an Attachment providing historical context and supporting rationale.

We appreciate your consideration of this request and welcome the opportunity to meet and discuss this matter in more detail. In the meantime, please do not hesitate to contact us for further information or assistance.

Sincerely,

Allegheny Health Network
American Association of Colleges of Pharmacy (AACP)
American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
American Society of Health-System Pharmacists (ASHP)
BD (Becton, Dickinson and Company)
ECRI
GS1 Healthcare US
Hematology/Oncology Pharmacy Association (HOPA)
Institute for Safe Medication Practices (ISMP)
National Community Pharmacists Association (NCPA)
New York State Council of Health-System Pharmacists (NYSCHP)
Omnicell
THRIV Coalition for IV Accuracy
Wolters Kluwer

ATTACHMENT

I. Public and FDA Comments in 2003 concerning "Would the Bar Code Be Required to Contain the Lot Number and Expiration Date?" (https://www.federalregister.gov/documents/2003/03/14/03-5205/bar-code-label-requirement-for-human-drug-products-and-blood)

Many organizations and individuals recommended that the bar code contain information regarding the drug's lot number and expiration date, and others have recommended phasing-in a requirement to have the bar code contain the lot number and expiration date.

FDA declined to require lot number and expiration date information in the bar code at the time of this regulation. In general, while lot number and expiration date information would make it easier to identify drugs that had been recalled or were expired, FDA neither found nor received data to show that the benefits of barcoding lot number and expiration date information would exceed the costs of putting that information in the bar code. There is, however, limited information on the extent to which patient safety is affected by and medication errors occur as a result of taking expired or recalled drugs. FDA reviewed data from its adverse event reporting system (containing 71,546 cases) and found 90 cases where patients received an expired drug and 21 cases where patients received a recalled drug. Expired drugs may become subpotent and might not have the intended therapeutic effect. They also may contain degradation products associated with aging. Products may be recalled for a variety of reasons including no active ingredient present in the product or contamination of the product that could lead to infection.

FDA also tabulated data from the Office of Compliance, Center for Drug Evaluation and Research, on the reasons for and the extent to which drug products have been recalled from the market. From fiscal year 1997 through fiscal year 2002, there were 1,230 recalls, of which 97 were Class I (reasonable probability that the use or exposure to the violative product will cause serious adverse health consequences or death) and 1,133 were Class II (use or exposure of the violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote). Despite the number of recalls for safety and health reasons, FDA received few reports of adverse events associated with the administration of a recalled drug, and they did not have reliable data to show how often these products were administered to patients.

Thus, based on the data available to FDA, it could not determine the magnitude of the public health problem associated with administering expired or recalled products, and they could not quantify the patient safety benefit associated with requiring lot number and expiration date information in a bar code.

Based on the evidence FDA had at the time and their obligation under Executive Order 12866 to choose regulatory approaches that maximize net benefits, the potential burden of encoding lot number and expiration date information appeared to outweigh

the potential benefit at the time. Consequently, the proposed rule did not require lot number and expiration date information in the bar code. FDA noted that they would continue to study the issue and invite comments and, more importantly, data on costs and benefits associated with requiring lot number and expiration date information in the bar code. If comments provide information and data to support requiring lot number and expiration date information, we may consider requiring that information with the barcoded NDC number as part of a final rule.

Although the proposed rule would not require the drug's lot number and expiration date to appear in the bar code, the proposed rule would not prohibit the inclusion of such information. In other words, FDA will not object if a manufacturer, repacker, relabeler, or private label distributor were to add the lot number and expiration date to its bar code or add such information in a machine-readable format provided that the lot number and expiration date information is accurate. In a meeting with PhRMA on August 19, 2002, the industry representatives suggested to FDA that they might add machine-readable lot number and expiration date information if a demand existed for it. FDA did not know how much more such drugs would cost (compared to drugs that only had the NDC number encoded in the bar code) or whether hospitals and other health care facilities would be willing to pay more for drugs that have the NDC number, lot number, and expiration date in a bar code or machine-readable code, but the meeting raises the possibility that market forces could lead to the inclusion of lot numbers and expiration dates in bar codes or other machine-readable formats.

II. Public and FDA Comments in the August 2011 Guidance for Industry titled "Bar Code Label Requirements Questions and Answers".

Can a firm use another automatic identification technology, such as a radio frequency identification chip or a two-dimensional symbology, instead of a linear bar code?

FDA stated that as a general matter, no. The final rule requires the use of a linear bar code to encode the NDC number on most prescription drug products and certain OTC drug products. However, we do not intend to object if firms voluntarily encode lot number and expiration date information, and we recognize that some firms might use other technologies to encode that additional information (response to comment 35, 69 FR 9120 at 9134-9135). In addition, FDA will consider requests from vaccine manufacturers who request to use an alternative regulatory program, comprised of alternative technology such as two dimensional symbology, that encodes, for example, the lot number and expiration date, because use of this technology may enhance health care providers' ability to keep records and report adverse events as required under the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) (42 U.S.C. 300aa-25(a)). In particular, FDA will consider such an exemption request under 21 CFR 201.25(d)(1)(ii) on the grounds that given the unique concerns regarding vaccines, an alternative regulatory program using alternative coding technology renders the use of a linear bar code unnecessary for patient safety. FDA recognizes that it may be infeasible for a vaccine manufacturer to implement alternate coding technology for childhood vaccines only, while retaining linear bar coding for its other vaccines due to practical considerations related to manufacturing and cost. We will therefore consider a

manufacturer's request for such an exemption for other licensed vaccines in addition to childhood vaccines.

Furthermore, FDA stated that they will be reviewing the bar code rule under Executive Order 13563, "Improving Regulation and Regulatory Review," and FDA will use the information received to assess whether the bar code rule is achieving its intended benefits as effectively as possible or should be modified. The Agency may revise this guidance, as appropriate, in connection with this effort (emphasis added**)**. As stated in the preamble to the final rule: Bar codes can help reduce or detect potential medication errors by enabling health care professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time. The preamble contemplated that linear barcodes, the use of scanning equipment, and computerized databases would be part of a system that could help reduce the number of medication errors that occur in hospitals and other health care settings.

The March 2003 proposal would not require the bar code to contain the drug's lot number or expiration date. In the preamble to the March 2003 proposal, FDA explained that they were unable to show that the benefits associated with encoding lot number and expiration date information exceeded the costs, so we proposed to omit lot number and expiration date information from the bar code (see 68 FR 12500 at 12507). However, FDA also said that they would not object if drug manufacturers, repackers, relabelers, and private label distributors decided to encode lot number and expiration date information voluntarily (id. at 12508). FDA stated that industry representatives had suggested that they might add such information if a demand existed for it (id.), but FDA did not know whether hospitals and other health care facilities would be willing to pay more for drugs that had lot number and expiration date information encoded in the bar code. FDA invited comments on the costs and benefits associated with putting lot number and expiration date information in the bar code.

Many comments urged FDA to require lot number and expiration date information in the bar code, but did not provide evidence to support their views. Instead, most comments declared that lot number and expiration date information would make it easier to identify recalled, contaminated, and expired drugs, would improve entries into medical records, or would provide greater patient safety. Other comments said we should phase-in a requirement to encode lot number and expiration date information over an extended time period, but did not discuss why a phased-in approach would alter the cost-benefit problem that we identified in the preamble to the proposed rule. Some comments would extend the rule's effective date to give firms more time to encode such information. Another comment urged firms to encode lot number and expiration date information, but only if the costs were not passed on to hospitals.

Other comments advanced different arguments for requiring lot number and expiration date information as part of a bar code. For example, one comment stated that the American Society of Hospital Pharmacists and others want lot number and expiration date information encoded, and so we should defer to them. Several comments said manufacturers should encode such information because they could do so at less cost compared to hospitals.

Several comments advocating the inclusion of lot number and expiration date information in a bar code argued that technology could encode such information. For example, one comment claimed that the information can be easily encoded using two-dimensional symbologies and noted that some manufacturers plan to encode such information voluntarily. Another comment noted that the GTIN, rather than the NDC number alone, could be used to provide additional patient safety information. Another comment declared that encoding lot number and expiration date information could be inexpensive because, the comment noted, firms already print the same information, in human-readable form, on packages.

In contrast, other comments supported our decision to omit lot number and expiration date information from the rule. Several comments conceded that the information could help trace recalled drugs and help with product inventory, but said that the information would not significantly reduce medication errors and that the costs of encoding the information would exceed the benefits. For example, one comment estimated that encoding lot number and expiration date information would cost $7,500 to $20,000 per manufacturer's line, excluding costs to verify the information. Several comments expressed concerns about the impact on production line speed. For example, one comment said that the online printing equipment that would be needed for encoding lot number and expiration date information is "highly ineffective and unreliable" at production speeds above 120 units per minute and that alternatives, such as preprinting labels, would present serious good manufacturing practice (GMP) concerns in verifying that the right label with the correct lot number and expiration date is used on the correct product. Another comment said that online printing and verification technology has not been demonstrated at production line speeds of 250 to 300 units per minute. A different comment listed various problems associated with online printing of lot number and expiration date information, such as adverse impacts on line speed and print quality, the need to develop unique bar codes for each packaging run, and limiting packaging options until printing and packaging technology becomes capable of supporting online product speeds and adequate print quality.

Another comment said FDA was correct to omit lot number and expiration date information from the rule because it would make bar coding more complex and perhaps discourage manufacturers from making unit-dose packages. The comment, along with other comments opposed to requiring lot numbers and expiration dates in a bar code, shared our view that the market would determine whether manufacturers and others encode lot number and expiration date information voluntarily.

One comment suggested that, if FDA decided to require lot number and expiration date information to be encoded, the information should only go on shipping cartons and not on individual packages because this would reduce the manufacturer's costs.

The comments also disagreed on how to interpret our recall data. The preamble to the proposed rule stated that we had examined the number of recalled drugs from fiscal year 1997 through fiscal year 2002 and that, while there were 1,230 recalls during that time period, there were few reports of adverse experiences associated with the administration of a recalled drug (see 68 FR 12500 at 12507). One comment said this data supported inclusion of lot number and expiration date information in the bar code

because Class I recalls represent a reasonable probability that the use or exposure to the drug will cause serious adverse health consequences or death, and 97 of the 1,230 recalls were Class I recalls. In contrast, a comment that opposed inclusion of lot number and expiration date information in the bar code said the data were not sufficient to show any public health problem resulting from the administration of recalled or expired drugs.

FDA responded that the final rule does not require lot number or expiration date information to be included in the bar code. As FDA stated in the preamble to the March 2003 proposal, the data available to FDA did not indicate the magnitude of the public health problem associated with administering expired or recalled drugs, and we cannot quantify the patient safety benefit associated with requiring lot number and expiration date information in the bar code (see 68 FR 12500 at 12507). The potential burden of encoding lot number and expiration date information appears to outweigh the potential benefit of encoding such information.

FDA emphasized that they did not dispute whether encoded lot number and expiration date information would be helpful in certain contexts that are unrelated to medication errors. FDA also did not dispute that the technology exists to encode such information or that certain firms have expressed their intent to encode such information. Nevertheless, while we recognize the strong desires expressed by some regarding lot number and expiration date information, FDA must also recognize the potential impact on manufacturers, repackers, relabelers, and private label distributors if we required them to encode lot number and expiration date information. The evidence before FDA indicated that the costs associated with encoding lot number and expiration date information, insofar as medication errors are concerned, exceed the benefits, so FDA declined to require such information as part of the bar code.

FDA reiterated that they will not prevent or prohibit firms from encoding lot number and expiration date information if they wish to do so, and we note that some drug manufacturers are encoding or intend to encode such information. FDA also reminded hospitals and other potential bar code users that lot number and expiration date information may be encoded in two-dimensional or other technologies, so if they intend to purchase drug products with lot number and expiration date information encoded, they should consider carefully their scanning or reading equipment purchases (see 68 FR 12500 at 12507).

Respectfully Submitted,

Jerry Phillips, R. Ph.
Former FDA, CDER Associate Director of the Office of Surveillance and Epidemiology and Acting Director, Division of Medication Error Prevention and Analysis