



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

June 11, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0204, FDA Proposed Rule on Bar Code Label Requirements for Human Drug Products and Blood

Dear Sir or Madam:

The Consumer Healthcare Products Association welcomes the opportunity to comment on the above captioned proposed rule issued by the Food and Drug Administration in the March 14 Federal Register (68 Fed. Reg. 12500 [March 14, 2003]). CHPA is the 122-year-old trade association representing manufacturers and distributors of nonprescription, or over-the-counter (OTC) medicines and dietary supplements. CHPA members manufacture OTC medicines that would be affected by the proposed rulemaking.

Summary. CHPA supports the intent of the proposed rule to add a bar code to many medications intended to be dispensed in hospitals. We support the agency's view that such a rule will help arm busy healthcare professionals with modern technology to help them avoid making crucial medication mix-ups and mistakes.

Eight areas are of particular interest in the proposed rule:

1. Coverage of OTC medicines "dispensed under an order" would benefit from clarification.
2. Coverage of OTC medicines "commonly used in hospitals" requires clarification.
3. Mandating use of an NDC number within the UPC complicates inventory systems and could add costs without corresponding benefits.
4. Packaging levels required to carry a bar code could complicate implementation.
5. FDA's views on other issues raised will impact implementation.
6. FDA's view that lot and expiration date elements are not indicated recognizes costs versus benefits.
7. Technology must be allowed to evolve.

8. FDA should consider limited exemptions from portions of 21 CFR 201.10(i) if needed to accommodate bar codes.

We will examine each of these subjects in turn.

1. Coverage of OTC medicines “dispensed under an order” would benefit from clarification. In the preamble to the proposed rule, the agency discusses the intended limited coverage of OTC medicines under the rule to those OTCs dispensed under a physician’s order, since these products may be more likely to contribute to medication errors. While we largely concur with this approach, additional or different language should be included in 21 CFR 201.25(b) to add clarity to the types of OTC medicines which would be covered. For instance, rather than using the phrase “dispensed under an order,” the phrase “dispensed upon a prescription of a practitioner licensed by law to administer a drug” would more clearly describe the type of order the agency intends: one by a doctor or other healthcare professional with prescribing authority. This should clarify any confusion over what an “order” is, since presumably any or all OTC medicines, including those the agency does not intend to cover, are provided to patients under what could be seen as some type of “order.”

The agency should also consider explicitly listing categories of OTC products the rule would not cover. For instance, the agency could exclude categories of OTC medicines not subject to dosage limitations, such as skin protectants or sunscreens. This would help tailor coverage to areas believed to be more likely contributors to medication errors. Even with a clearer definition of what is covered under dispensing orders, any OTC could be dispensed under a prescription, yet that is clearly not FDA’s coverage intent.

2. Coverage of OTC medicines “commonly used in hospitals” requires clarification. We agree that OTC medicines commonly used in hospitals that are in fact intended for hospital use (and dispensed by a prescription) should be covered by the rule. But proposed 21 CFR 201.25(b) would inadvertently sweep a far larger range of OTC medicines into the rule’s coverage. Packaging designed for institutional use, package labeling for institutional use, and explicit marketing or promotion to hospitals are all appropriate indicators that an OTC medicine is “commonly used in hospitals.” But the proposed rule goes three steps further. First, the rule’s coverage would be triggered by any one of those three indicators, not all or a combination of them. Second, and even more importantly, triggering coverage through sale to a hospital would open up products which are re-sold to hospitals to coverage without clarifying that the manufacturer, who would no longer control the product in the resale scenario, would no longer be responsible for coding. Third, the proposed rule implies that, when coverage is triggered, all package varieties of that OTC drug product would now be covered. For example, if a hypothetical drug product, “Pain Reliever Z,” came in a 500-count institutional use package, with single use packets of 2 tablets each within the package, as well as 24 and 50 count packages intended for retail sale, not for institutional use, all three packages for the single drug product would appear to be covered under the rule. The agency’s preamble discussion, in contrast, recognizes coverage of such a vast array of OTC drugs would not advance the rule’s purpose, since they are used outside of a hospital environment.

We suggest that, rather than the proposed definition for “commonly used in hospitals,” the coverage trigger should include a combination of two or more indicators: packaging designed for institutional use, package labeling for institutional use, or marketing or promotion (including through sales catalogues) to hospitals. Second, we suggest that the rule make clear that it is the package level so designed, labeled, and/or marketed/promoted that falls within the scope of the rule, not the open-ended drug product scope of the proposal. Third, we suggest that the rule be more explicit as to who is responsible for coding: the party designing, labeling, and/or marketing/promoting and ultimately, therefore, selling to the hospital, which may or may not be the manufacturer. This would assure that the agency’s concern about intentional sale to a third party for resale to hospitals in an attempt to circumvent the rule was addressed.

We would also suggest that, since hospitals are not required to use scanners, catalogues or price lists which include an institutional use package covered under the rule be able to include alternative packages not covered by the rule. If a hospital is not using scanners, there is no need to mandate that it purchase a package that may carry the additional cost of rule compliance.

3. Mandating use of an NDC number within the UPC complicates inventory systems and could add costs without corresponding benefits. The Associated Press story on the proposed rule squarely stated the case: “Supermarket-style bar codes will soon be required.” Yet the agency has chosen to not allow true supermarket-style bar codes – the UPC – and to instead require the NDC number. As we discussed at the July 26, 2002, FDA meeting on bar codes and in subsequent related comments to this docket, most often, companies use UPCs as a Global Trade Item Number (GTIN) on OTC medicines. This is simply a unique number within the Uniform Code Council (UCC) system, which works well for the consumer healthcare industry. While the vast majority of products have more than one size or shelf-keeping unit (SKU), and each SKU has an NDC number, some companies have more than one UPC for a given SKU, in order to track different modes of distribution and sales for the product. The UPC system easily allows companies to create global unique numbers without requesting extra NDC numbers. Conversely, other companies change NDC numbers more often than the UPC. This is for name, formulation, or manufacturing changes. In any event, companies need to track SKUs differently to assess account sales, promotions by package size, inventory management, and tracking in case of a product tampering or recall. The UPC (or GTIN) system is essential for a robust, competitive business environment.

Further, changes in inactive ingredients in OTC formulations would not require a change in the UPC. Instead, different suffixes or lot numbers are used for control purposes to differentiate between product formulations, but the basic UPC need not change. A different UPC for any OTC medicine results in retailers regarding the product as a new item which has significant logistical and financial consequences. Retailers re-code warehouse, shelf code, and other control systems for each new item and manufacturers are charged substantial fees to cover the cost of this activity. These fees are called by various names such as new item fees, maintenance fees, or set-up fees. If the NDC is required to be used as the UPC, manufacturers will incur thousands of dollars of unnecessary extra “new item” costs because a different NDC is required for even minor formula modifications.

Mandating a marriage between the UPC and NDC, or requiring both codes, would severely disrupt the current, efficient system for OTC medicines. To comply, a firm may need to establish a parallel inventory system, which would add unnecessary costs and complexities. A parallel system doesn't solve the disruption in pre-existing systems. Rather, it adds another layer of complexity in distribution. Further, the use of two codes on one package is simply infeasible. False readings of the wrong bar code would create more confusion and the potential for more errors – the very issue the rule seeks to address. We believe that the UPC is the only necessary product identifier that should be bar coded on a product. The relationship between the UPC and NDC can be handled through a database, and the UCC system is sufficient for controlling unique numbers.

If OTC medicines were to exclusively use NDC numbers within their bar codes, workload and related expense would be added for FDA, since there would likely be a need to issue new NDC numbers, and to issue NDC numbers more frequently, as package alternatives or distribution modes change. Further, using NDC numbers in OTC bar codes would reduce the available inventory of such numbers. Workload and related expense would also be added through the supply chain, as incorporating the NDC into the bar code would likely occur at all levels of packaging, including levels such as shipping containers that today have bar codes that do not frequently change.

These challenges can be avoided by allowing the continued use of existing UPC bar codes. While the agency has expressed the concern that allowing firms to continue to use their own unique identifying numbers (such as the UPC without the NDC) could be confusing and more difficult, we respectfully disagree. Implementation by hospitals of any scanning system will require software programming by vendors and communication with database providers, just as retailers do today. Those retailers and manufacturers already work with and through virtually an entire industry of scanner suppliers, database subscription services, and other vendors using bar codes under the UCC/EAN system. Leveraging from this existing system will be more efficient than requiring a new one.

We also note the agency's intent to revise regulations for NDC numbers. This revision will raise a new round of questions and work requirements when, again, using existing systems can better avoid such a situation.

4. Packaging levels required to carry a bar code could complicate implementation. We note that there could be a cascading effect if bar coding of OTCs dispensed under a prescription and commonly used in hospitals ends up driving new packaging. For example, new packaging may require stability testing and validation of packaging process. Further, packaging changes for OTC medicines under new drug applications would require manufacturing supplements for FDA approval. We raise these points as illustrations of the need for a three year implementation period, as the agency proposes.

5. FDA's views on other issues raised will impact implementation. The agency's responses to clarifying what OTC medicines are covered and the use of UPCs versus NDCs will

have a dramatic impact in how readily manufacturers can add bar codes at lower packaging levels.

Ultimately, we believe the three year implementation period will be much more feasible with the modifications suggested in the first three sections of these comments. We would also note, however, that anticipated changes to the agency's rules for NDC numbers will add another level of complexity to compliance. Without knowing what those changes will be, we cannot assess an appropriate compliance timeframe.

6. FDA's view that lot and expiration date elements are not indicated recognizes costs versus benefits. We concur with FDA's view that the inclusion of elements within the bar code to trigger references in related databases to lot numbers and expiration dates is not indicated. As the agency notes, such a requirement would add costs, including through the impact on production line speeds, without a medication error-related benefit having been shown. Further, for high speed OTC medicine production lines that are common in our industry, many of the complex GMP validation issues that such a requirement would raise have simply not been explored.

7. Technology must be allowed to evolve. While the proposed rule would require use of linear symbology, such a limitation on symbology would freeze the rapid evolution of technology in this area. We therefore welcomed FDA's invitation to comment on whether additional symbologies should or could be included. CHPA believes a rule which is open-ended as to the coding technology to be utilized, while tying the utilized technology to a known, widely used standards setting organization, would be the most efficient approach. Adopting technology widely used in other industries is part of the driving force behind the proposed rule that makes it feasible. As discussed in section 3 on NDCs contrasted with UPCs, the Associate Press story put it best: "Supermarket-style bar codes will soon be required." Mass merchandisers, pharmacies, food stores, and many other retailers, as with manufacturers of products sold in those and other outlets, work with and through UCC/EAN in continuously developing standards over bar code symbologies. In turn, virtually an entire industry of suppliers and vendors exists to supply retailers and manufacturers with goods and services they need to roll-out products with the symbology to meet demand as efficiently as possible. Why not tap into that already existing and robust marketplace? The rule should be open-ended on the symbology to allow the fairly near term retail use of data matrix symbology to be carried over into other settings. FDA can assure that the range of symbologies used is not overly burdensome to hospitals (which in any event are not required to use scanners) by maintaining the provision in proposed 21 CFR 201.25(c)(1) relying on UCC/EAN standards, while removing the linear requirement.

If the agency believes this approach does not sufficiently reduce the risk of multiple symbologies in the marketplace at one time, the agency could consider removing the linear requirement from the rule, but establishing a compliance policy guide to list currently acceptable symbologies. The compliance policy guide (CPG) approach would allow more timely, less cumbersome amendments to a symbology list. FDA's tamper-evident packaging regulations are an example of a generalized rule accompanied by a CPG with more specificity, where the

regulations allow any packaging system that meets the tamper-evident standard, and the CPG provides a list of packaging technologies that are capable of meeting the standard. (See 21 CFR 211.132 and Compliance Policy Guides sec. 450.500.)

8. FDA should consider limited exemptions from portions of 21 CFR 201.10(i) if needed to accommodate bar codes. While the agency states that it does not intend to allow for individual exemptions to the rule, the agency should consider the need for trade-offs between bar codes on very small labels contrasted with the minimum required label elements of 21 CFR 201.10(i), and have a mechanism to provide relief for packages intended only for hospital use.

For example, an exemption should be possible for blister unit dosage forms used in a hospital setting. The manufacturer should be able to delete required information as appropriate from among the established name, address of manufacturer, special characteristics of the dosage form (chewable, sustained release, etc.), or statement of identity, provided that the removal of information is needed to allow the bar code to fit on the individual blister unit, and all the required information appears on the exterior carton. Further, all removed information could be accessed through the database supporting the scanned bar code.

Conclusion. Clarifying what OTC drug products are covered by the rule and allowing the use of the current UPC bar coding system will more efficiently ensure that such OTC medicines in hospital-settings meet the intent behind the rule: to help provide busy healthcare professionals with another tool to help avoid medication mix-ups and errors.

Sincerely,

David C. Spangler
Vice President – International &
Assistant General Counsel

cc: Tom McGinnis, Office of Policy, Planning, and Legislation
Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23)

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