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PhRMA

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

Re: Docket No. 02N-0204; Bar Code Label Requirement for Human Drug Products and Blood; Proposed Rule; 68 Federal Register 12500

Dear Sir/Madam:

The following comments on the above noted proposed rule are submitted on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. Our member companies are devoted to inventing medicines that allow patients to lead longer, happier, healthier, and more productive lives. In 2002, our members invested over $32 billion in the discovery and development of new medicines.

At the public hearing on bar codes that the Food and Drug Administration (FDA) held last summer, PhRMA voiced its support for a proposed rule that would require certain human drug and biological product labels to have bar codes. PhRMA believes that bar codes containing the National Drug Code (NDC) number, a unique product identifier, will provide a new technological approach that will reduce medication errors in hospital settings and, by extension, will improve patient safety in our nation's healthcare system. In June of 2001, the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) issued a report based on an earlier workshop that urged the establishment of a uniform bar coding program for drugs. PhRMA, a founding member of NCC-MERP, assisted in convening the workshop and was a signatory to that report.

As evidenced by these initiatives, PhRMA is committed to the highest standards of patient safety. Indeed, as researchers and developers of lifesaving medicines, the safety of the patients who take our medicines is paramount. We appreciate FDA's work to reduce bedside medication errors and hope that the proposed rule on bar coding will accelerate the adoption of safety-improving information technologies throughout our healthcare system.

PhRMA values the work FDA has put into the proposed rule and appreciates the spirit of collaboration which has guided this effort. In order to maximize the utility of the bar codes proposed, and, by extension, ensure the highest levels of safety during the medication dispensing process, we suggest the following technical modifications to the proposed rule prior to finalization. PhRMA's suggestions for such modifications and our comments on the proposed rule are detailed in the following sections.

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1. Bar Code Standard and Data Elements

PhRMA supports a standard bar code containing the National Drug Code (NDC) number on prescription drug packaging destined for hospital administration. Standards developed by the Uniform Code Council (UCC/EAN) are generally recognized, and equipment is readily available to read such bar codes. PhRMA encourages the Agency to issue a Final Rule that is flexible enough to accommodate new technologies as they become available; this ensures that improvements may be readily adapted without the need for revised regulations. Minimally, the Final Rule should allow flexibility to select from any UCC/EAN bar code symbology or data carrier. This flexibility will allow sponsors to consider alternatives when label space is severely limited (e.g. single-dose vaccines and injectables).

The UCC/EAN standard is moving towards a Global Trade Identification Number (GTIN), whose data carrier or bar code accommodates a 14-digit data structure. The GTIN may be encoded in EAN/UPC, ITF-14, UCC/EAN-128, and RSS symbologies, all of which are being or will be used for pharmaceutical products. In particular, RSS-14 is a very small bar code that will be of great use in bar coding solid oral dosage unit dose packaging. The ten digit NDC number can easily be incorporated into the GTIN data structure, thus meeting the intent of the FDA proposed rule.

PhRMA agrees with FDA's finding that only the product identification bar code or NDC number will materially contribute to the reduction of medication errors. In PhRMA's comments to FDA last summer, we questioned whether lot number and expiration date were critical to achieving this goal. Additionally, such secondary data elements can only be incorporated in a composite code. These data elements change from batch to batch in the manufacturing process such that high-speed on-line printing may not be possible. PhRMA estimates that it would take five years to fully incorporate these data elements into a small composite bar code. This is not acceptable in terms of the current need to address medication errors. PhRMA notes that there is nothing in the current proposed rule that would prohibit manufacturers from incorporating these secondary data elements into label bar codes should the technology evolve and the need to do so become more evident with time.

2. The Need for a Small Container Waiver

FDA notes in this proposed rule that they have declined to create an exemption provision but request comment on whether any specific product or class of products should be exempt from the bar code requirements. A survey of PhRMA member companies indicates that while all are committed to implementing bar codes on medicines designed for use in the hospital setting, there are a number of products currently manufactured whose immediate packaging simply precludes the inclusion of a bar code under this Proposed Rule. Such products include solid oral dosage forms in blister packs, pre-filled syringes, suppositories, and small vials that are either packaged alone or in multi-vial packs. There are also kits that contain both the active drug product and a diluent. Immediate packaging that comes in contact with active drug product is carefully evaluated and the manufacturing process controlled to assure proper quality, purity, and potency of the pharmaceutical/biological. Redesign of such packaging to accommodate the placement of a bar code is not trivial and in certain cases, may not be possible. Additionally, changing the immediate container

packaging may, in some cases, affect drug product quality, purity and potency, necessitating the filing of a supplemental New Drug Application. If two dimensional codes are not allowed, it will be impossible for some products packaged in small containers to comply with the regulation as even the smallest linear barcode in the EAN.UCC standard; RSS will not have sufficient space to be read. In such cases, a significant period of time may pass before the company can come into compliance with this proposed rule. PhRMA strongly believes that there must be a waiver or exemption process established for such products. To this end, PhRMA proposes the following two changes in the proposed regulation (proposed new language is underlined):

§ 201.25 Bar code label requirements

(a) Who is subject to these bar code requirements? Except where waived by the Commissioner as in subsection (d), manufacturers, repackers, relabelers, and private label distributors.....

and,

(d) What products are subject to waivers under this section? The Commissioner may waive the requirements for a marketed drug product described in subsection (b), if there is insufficient room on the immediate container to affix a bar code using any standard available as of the implementation date of the final rule. A request for a waiver shall be accompanied by a sample of the packaging, reason for the request, and alternative packaging (if available) that meets the intent of this rule. Such alternative packaging could be an outer package containing the applicable bar code. The Commissioner shall issue a decision on all waiver requests within sixty days of application.

Many solid oral dosage form blister packs can accommodate a bar code provided FDA grants an exemption from certain labeling regulations in 21 CFR Part 201.10(i). This section of the pharmaceutical labeling regulations requires the proprietary name of the drug, the established name, an identifying lot or control number, the name of the manufacturer, packer, or distributor on the packaging of containers too small to otherwise accommodate all the information required to comply with the FD&C Act Section 502(e)(1)(A)(ii) and (B). For example, eliminating this requirement for unit dose blister packaging will, in many, cases free up space for the bar code and allow greater legibility for the product name and dosage strength. This past summer PhRMA submitted to the FDA an example of printing both with and without the manufacturer's name. PhRMA strongly believes that FDA should alter the wording of the final regulation to make this possible. Proposed language to accomplish this is as follows:

§ 201.25(c)(2) The bar code must appear on the drug's label as defined by section 201(k) of the act. Any drug complying with the provisions of this section are exempt from the provisions of Sec. 201.10(i)(1)(iii and iv) if the packaging size is such that the other required information is not easily readable.

The above comments in this section also apply to the biological labeling requirements that are found at 21 CFR 610.60.

3. Over the Counter (OTC) Drug Products

OTC drug products pose a special issue relative to this proposed rule. At present the vast majority of OTC products are labeled with an all numeric Universal Product Code (UPC) in bar code format that is used by retail stores to facilitate point-of-sale transactions with automated check-out counters. The encoded UPC number may or may not be a manufacturer's NDC number. Thus, there is a significant commercial issue that will not permit replacing the UPC number with an NDC bar code. Retail facilities will not stock products that do not have a bar code that meets their needs. Thus, manufacturers of OTC drug products would have to potentially maintain a duplicate inventory of packaged drugs: those with a UPC bar coded and those with an NDC bar code. Shipping logistics will also have to be carefully managed so that the NDC bar coded package does not get inadvertently shipped to the non-hospital retail setting and vice versa.

A second consideration is that many OTC solid oral dosage forms come in blister packs, such packs may not be perforated limiting their use in "unit dose" dispensing in a hospital setting (these blister packs may also have size limitations, preventing routine bar coding as noted in 2 above). PhRMA believes that the regulation needs to be modified to accommodate those OTC products whose bar code does not already incorporate the NDC number.

As FDA notes in the proposed rule, the Agency intends to establish a database of NDC numbers that will serve as the master repository for hospitals to use as they establish their computerized database linking the bar code to the product. PhRMA is most interested in how this database will be constructed and what FDA's timing for establishment will be. This is critical to moving this initiative forward as the database will assure that there are no duplicate NDC numbers. It should be possible for such a database to accommodate <u>both</u> NDC and UPC numbers following assurance that there are no duplicate numbers. A reporting mechanism would have to be developed for manufactures to pass both the NDC and UPC to the FDA database.

To this end, PhRMA recommends the following change to the Proposed Rule:

§ 201.25(c) what does the bar code look like, and where does the bar code go?

(1) Each drug product described in paragraph (b) in this section <u>except for those OTC drug products described in subsection (3)</u> must have a bar code that contains, at a minimum the appropriate National Drug Code (NDC) number ~~in a linear bar code~~ that meets Uniform Code Council (UCC/EAN) standards.

<u>(3) OTC drug products need only carry the Universal Product Code (UPC) number within the bar code if the hospital packaging is identical to that available in the retail marketplace provided the number is not in conflict with an already assigned NDC number. Manufacturers of such products shall notify the FDA of the UPC number within 30 days of implementation of this regulation.</u>

4. Economic Impact Analysis

   To comply with the regulation, PhRMA member companies expect to upgrade existing and purchase new packaging equipment - initiatives that will require substantial investments and likely will exceed FDA's initial cost estimates. The pharmaceutical industry, however, believes the expected reduction in medication errors is well worth the investment. In the interest of patient safety, we are absolutely committed to implementing the rule.

PhRMA Responses to the Specific Questions Posed by the FDA

On page 12529 of the proposed rule, the FDA requests responses to a series of questions. For clarity, the text of each question is reproduced below followed by PhRMA's response.

1. *Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes.*

   PhRMA does not believe that there should be a requirement to bar code physician samples, as the likely benefit of such a requirement would be minimal at best. Such samples typically are not designed for administration by hospital pharmacies, the intended focus of this proposed regulation. However, sponsors should be permitted to voluntarily bar code physician samples with the NDC number if proven beneficial for tracking samples. Additionally, in more technologically advanced offices, bar codes could be utilized to link samples to a given patient.

2. *The risks and benefits of including vaccines in a bar code rule.*

   PhRMA believes that vaccines should be included under the scope of this proposed rule.

3. *What terms we should use to describe OTC drugs that should be subject to this bar code requirement.*

   See the response to OTC products in the previous section.

4. *Information on the costs and benefits associated with putting lot number and expiration date in the bar code.*

   PhRMA agrees with the Agency's statement that there is no evidence that supports the benefit to bar coding lot number and expiration date with respect to reducing medication errors.

5. *Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.*

   As PhRMA stated in its comments in the previous section, the regulation should refer to UCC/EAN standards but not specify a linear bar code. As currently written, the proposed rule limits manufacturers to existing linear standards, making it difficult to meet future information needs. In addition, PhRMA is aware that the vaccine industry is moving towards

a different standard because of increased information requirements from the Centers for Disease Control (CDC).

6. *Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies.*

   Bar code readers exist that can read all of the potential standards.

7. *Whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology).*

   As in our response to number 5, above, PhRMA does not believe the standard should be restricted to a linear code.

8. *Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary. In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?*

   PhRMA is committed to the use of bar code technology for the prevention of medication errors. However, there is a subclass of products that is not amenable to bar coding. The need for an exemption or waiver for these products and proposed regulatory language is discussed in the previous section.

9. *Whether the implementation period for a final rule can and should be shortened from 3 years to some other specific time period.*

   PhRMA supports an implementation period of 3 years following publication of the Final Rule. This will allow manufacturers sufficient time to incorporate bar codes on all hospital products as well as time for our healthcare partners to fully embrace the technology.

10. *Whether we should require the use of ISBT 128 for blood products, a specific symbology that is consistent with that required for drugs in proposed §201.25, or machine-readable symbols" as approved by the Director of CBER.*

    PhRMA has no comments on this issue.

11. *How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital.*

    PhRMA has no comments on this issue.

12. *Whether any of the alternatives discussed in the economic analysis have merit.*

    With the suggested changes in these comments PhRMA supports moving forward with bar coding of pharmaceuticals as an effective way to minimize medication errors.

PhRMA trusts that these comments are useful to the FDA as the Agency moves forward to finalize this important regulation. Our industry is committed to moving forward on this matter as it represents an important step in reducing medication errors in hospital settings.

Sincerely,