Fresenius Medical Care NA

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

June 10, 2003

SUBJECT: **Docket No.: 02N-0204**
Bar Code Label Requirements for Human Drug Products and Blood

RE: **Exemption Request** and **Comments** from Fresenius USA Manufacturing, Inc. (dba Fresenius Medical Care North America)

Dear Sir or Madam:

Fresenius USA Manufacturing, Inc. (dba Fresenius Medical Care North America --FMCNA) respectfully submits the following comments in response to the Food and Drug Administration's proposed rule making published in Federal Register Docket No. 02N-0204, dated March 14, 2003.

FMCNA commends FDA on its initiative to reduce medical errors. We, along with our healthcare industry partners, continually seek to promote efforts that improve the safe delivery of quality medical care products to patients. Yet, we believe that the proposed rule, which amends 21 C.F.R. Part 201, §201.25 and seeks to reduce medical errors through the use of bar codes, is too broad in its scope. As proposed the rule would require bar coding to the unit level for certain regulated product types, including all prescription drugs.

Section VII.B, Objective of the Proposed Rule, states the proposed rule "is to enable the health care sector to utilize technological solutions to reduce preventable adverse drug events (ADEs) associated with medication errors in hospitals". Section VII.D further defines the rule as applicable to "...drug products dispensed pursuant to an order and commonly used in hospitals, and all human blood products." However, as written, Section II.A of the rule states it is applicable to manufacturers of human prescription drugs who are required to register and list. FMCNA is a manufacturer of Rx drug products and we are required to register and list. However, due to our unique, home patient customer base we believe our Rx drug products do not require a barcode.

Our attached comments are the basis for our request for clarification and an exemption from this proposed bar code rule. **We are seeking an exemption for prescription drug products direct shipped from the original manufacturer, Fresenius Medical Care North America, to our home patients.**

Sincerely yours,

Dale M. Kapp; Supervisor
Regulatory Affairs

Thomas J. Raubach, Esq.
Law Department

Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420-9192

02N-0204 C 71

RE: Docket No.: 02N-0204, March 14, 2003
Bar Code Label Requirements for Human Drug Products and Blood

INTRODUCTION:

As part of the pharmaceutical manufacturing industry, Fresenius Medical Care North America (FMCNA) is committed to the health of our patients and the safe use of our products therefore we welcome endeavors which when implemented ensure the intended use of our products so that they do not cause patient harm, including those resulting from a medical error. In concurrence with FDA, we too feel the proposed barcode regulation has utility in most situations namely, to quote FDA's Statement of Need, to reduce "deaths due to medical mistakes made by health care professionals".

The results of implementing the bar code rule should be the application of effective practices and beneficial approaches for the reduction of medical errors. With that aim in mind, we believe that the proposed rule, which amends 21 C.F.R. Part 201, §201.25 and seeks to reduce medical errors through the use of bar codes, is too broad in its scope.

We are taking this 60-day comment period associated with the FDA proposed rule for *Bar Code Label Requirements for Human Drug Products and Blood* as an opportunity to bring to light the specific distribution of FMCNA drug products that needs clarification, and that we believe should be exempted from the scope of the proposed rule.

EXEMPTION REQUEST:

FMCNA herein requests an exemption from the proposed bar code rule, which amends 21 C.F.R. Part 201, §201.25 and seeks to reduce medical errors through the use of bar codes. We are a registered manufacturer and, as required, we list our human prescription drug products; therefore, as proposed the rule would apply to our prescription drug products. We request that an exemption be included for prescription drug products that are typically direct shipped from FMCNA, the original manufacturer, to home patients. Therefore, we specifically request an exemption from the requirements under proposed Section §201.25(a), §201.25 (b) and §201.25 (c)(1) of the proposed bar code rule.

Proposed § 201.25 (a)--*Who Would be Subject to the Proposed Bar Code Requirement?*
As written this section proposes to include all manufacturers, repackagers, relabelers, and private label distributors of human prescription drug products and OTC drug products; other than those exempt from the establishment registration and drug listing requirements.

Proposed §201.25 (b)--*What Products Would Have to Have a Bar Code? What Products Would the Rule Cover?*
This proposed rule covers all prescription drug products, including biological products (including vaccines), but excluding physician samples; all OTC drugs [distributed to hospitals]...blood and blood components.

Proposed §201.25 (c)(1)--*What Would the Bar Code Contain?*
As with §201.25 (b) above, this section would also require the bar code to contain, at a minimum, the drug NDC number.

BASIS for EXEMPTION REQUEST:
Fresenius Medical Care North America (FMCNA) is a vertically integrated company structured as a product manufacturer, a product distributor and a healthcare service provider. FMCNA manufactures and distributes a peritoneal dialysis (PD) solution drug product packaged in individual flexible bags. The patient receives a single, specific PD solution prescribed by their physician.

FDA states it proposes to cover all prescription drugs "because we are unaware of any prescription drugs that are not used in hospitals". FMCNA's peritoneal dialysis solution drug products are not typically used in hospitals. Aside from product sent to FMCNA and other clinics to be used for patient training purposes, the typical environment for use of our product is the patient's home. Our individual flexible containers are delivered directly to our patients at the case level. Like OTC drug manufacturers whose drugs you propose to exempt if they are not distributed to hospital settings, FMCNA's drug should also be exempted under the bar code rule. Our typical customer base, the home patient, does not have the bar code scanners required to verify receipt and administration of the correct drug product. Adding barcodes to our specific drug products does nothing to further assure the right patient, right drug, right dose, or right time for drug administration. Further support for this exemption request is contained in our comments below.

COMMENTS:
FMCNA is responding to FDA's request for comments, that was published under section VIII.8 in the above-cited docket. The section states, ***"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...."***

Proposed Sections §201.25(a) and §201.25 (b)
FDA cites Section 701(a) of the Act, as authorization to issue regulations for the efficient enforcement of the Act. We believe there is a lack of efficiency when applying the proposed barcode regulation to FMCNA PD Solution drug products. This is due to the specific environment in which our drug is used, and to the lack of any benefit from bar coding derived by our home patients. In this circumstance, bar coding does not reduce medical errors since, in this situation, it does not increase assurance of accurate medication administration; and so, does not further efficient enforcement of the Act.

We believe that barcoding is appropriate for commercially available drug products that traverse a multi-leveled distribution network. Such networks include for example; wholesalers, hospitals, HMOs, healthcare clinics, and other such care facilities and their many internal departments where the pathway for drug product distribution to the patient is indirect. We agree that barcoding is an effective means of improving this indirect transfer of drug products where various medical product, supply handlers exist between the original unit dose manufacturer and the patient/user at such facilities.

We do not believe that barcoding is appropriate or adds to the efficient distribution of prescription drug products that are sent directly from the original manufacturer to the home patient. In essence, delivery to the patient is directly after the product is obtained from our

manufactured inventory. Hospitals, physicians, nurses, and pharmacists external to our company do not take possession of our prescription drug prior to the patient's in-home self-administration. Additionally, there is none of the usual repacking or relabeling that hospitals employ prior to dispensing the drug. In the instance of our Rx drug product, its distribution network to the unit dose usage level is not the multi-leveled product handling typically encountered, and so is not associated with the handling issues that cause the potential for medication errors. Therefore, we strongly feel that for our specific type of manufacturer-direct-to-patient product handling, barcoding would not add to drug handling safety and prevent medical errors-- the intended scope of the proposed barcode regulation. In our particular circumstance, FMCNA feels and FDA has stated in the proposed rule that, current good manufacturing practices are sufficient to control the mandated inventory and tracking practices applicable to this level of drug product distribution. FMCNA currently places barcoding on the product insert (catalog number), and case (catalog number with current implementation of lot and expiration date) to assist with product inventory, receipt (at FMCNA distribution centers) and stocking.

As home users of these products, our patients do not have equipment capable of reading barcodes nor a reason to purchase such equipment. We find that FDA concurs with our position since, when discussing the rationale for not requiring bar coding on drug samples, FDA states that they "do not believe that physicians or patients would have or be inclined to buy bar code scanners for their own use in the immediate future."

Proposed Section §201.25(c)(1)
FDA states: "A bar code requirement for human drug products and biological products would be consistent with, and aid in the efficient enforcement of, sections 501 and 502 of the Act. For example, if the bar code merely contained the drug's National Drug Code number, the bar code would identify the manufacturer and the drug, and this would be consistent with sections 502(b) and 502(e)(1)(A) of the Act."

FMCNA drug products have always contained the required drug product information, including the voluntary NDC number. We believe that although not in bar code form, such information as currently supplied continues to meet requirements of the above-mentioned sections of the Act, in the most efficient way for our specific drug user.

The barcoding is requested down to the immediate unit of use packaging as defined in the USP NF. This means the drug product flexible bag. Yet, users of our Rx products receive our products direct shipped at a per case minimum. Our product cases each contain only one drug product. Therefore, in such an environment, if the drug is removed from the case for storage, this would typically be done at the patient's home and no mix up of medication should result nor, would this unlikely occurrence be addressed by a unit bar code requirement. Cases are shipped directly to the patient, and they do not have the capability to read barcoding from either the case or the unit label. We wish to state that we realize that drugs shipped to home patients from mail order outpatient pharmacies may benefit from barcoding, since these network of pharmacies have multiple owners who are an interim drug handler in the manufacturer-to-patient supply chain.

We agree with FDA that all appropriate measures should be taken to prevent medication errors. Some measures currently utilized by industry to reduce medical errors of health professionals include medication guides and drug/disease specific education programs. FMCNA does provide a patient training program that is specific to our type of drug product. We are handling the costs associated with such a training program, and feel its costs are justified and are more appropriate to our typical type of manufacturer-direct-to-patient drug product distribution. The cost of placing a readable NDC barcode on our PD Solution flexible bag, immediate container is significant and no value to the patient will be derived in terms of reducing medical errors.

The bar coding proposed when applied to our products will not result in improving the efficiencies in the safe delivery of quality medical products to patients, in a measurable medication administration benefit to our patients, in a significant decrease of overall morbidity and mortality related to drug medical errors, in ensuring proper use of products found safe and effective, or add to the operating efficiencies of hospitals, HMOs, healthcare clinics, other such care facilities. Adding bar codes to our PD drug solution products will not further FDA's primary focus which "is to help reduce the number of medication errors occurring in hospitals".

Fresenius Medical Care North America believes the above comments offer sufficient reasons for **clarification in the final rule of an exemption for prescription drug products that are not typically used in a hospital setting, but rather shipped directly from the original manufacturer to the home patient**. Thank you for the opportunity to comment on this rule.

Sincerely yours,

Dale M. Kapp

Dale M. Kapp; Supervisor
Regulatory Affairs

Thomas J. Raubach, Esq
Legal Department

:dmk