

C B. FLEET COMPANY INC 3 1 12 14 11 15

June 6, 2003

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

Re: Docket No. 02N-0204: Bar Code Label Requirement for Human Drug

Products and Blood

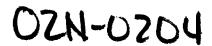
Dear Sir/Madam:

C. B. Fleet Company, Inc. ("Fleet"), wishes to comment on the proposed rule titled above (<u>Federal Register</u>/Vol. 68, No. 50/Friday, March 14, 2003, pp. 12500-12534). As a manufacturer of OTC drugs and cosmetic drugs, Fleet has a substantial interest in the consequences of any final rule on this topic.

Fleet agrees with the agency's objective of reducing the number of medication errors in hospitals and other health-care settings. Fleet also sees advantages in a system of positive identification of drugs that are administered to patients in hospitals.

Fleet concludes that the agency intends to group Fleet's products with prescription drugs and those OTC drugs that are "dispensed under an order and are commonly used in hospitals" (Proposed 201.25). By "commonly used in hospitals" the agency means OTC drugs that are "packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals" (ibid.).

Fleet sells a number of OTC products that are used in hospitals. With one exception* these products are distributed in their retail containers and not labeled for hospital or any institutional use. The products of concern in this comment are ready-to-use enemas, suppositories, prep kits (boxed bowel-cleansing kits comprising a laxative, a bowel cleanser, and an enema), medicated topical creams and powders, medicated pain-relieving pads and medicated douches. In addition, Fleet has a line of oral dosage forms (saline laxatives, stimulant laxatives, stool softeners, oral lubricant laxatives) which have a proven safety record within the current practice of medicine. Because each of these products is so distinctive in form and so clearly labeled, a mix-up with any other drug or a medication error would be exceedingly rare. In addition, each of them is already barcoded with the Universal Product Code (UPC) so as to facilitate identification.





Fleet further comments that the extension of a bar-coding system to the types of distinctive products they manufacture will place considerable burdens of cost on Fleet without the desired commensurate gain in safety.

Fleet thanks the agency for this opportunity to comment on the proposed rule.

Sincerely yours,

C. R. FLEET COMPANY, INC.

Sarah S. Post

VP of Scientific Affairs and Administration

SP:fbh

* To some hospitals, Fleet distributes individual ready-to-use enema bottles packed one (1) to a box, labeled for institutional use. The individual bottles are labeled in the same way as the retail enemas.