



January 26, 2007

Docket Officer
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20857

RE: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs. RIN 0910-AA49; Docket No. 2005N-0403 [71 Fed. Reg. 51276, August 29, 2006]

Dear Docket Officer:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on the Food and Drug Administration's (FDA) Proposed Rule: *Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs* (proposed rule or proposal), 71 Fed. Reg. 51276 (Aug. 29, 2006).

HDMA represents the nation's primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 144,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDMA members serve as the central link in a sophisticated national supply chain. As such, we have a responsibility to work closely with our supply chain partners to safeguard patient health. We take this mission very seriously, and we support manufacturers, pharmacies, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDMA appreciates FDA's effort to clarify its regulations governing drug establishment registration and listing. HDMA supports much of the proposed rule and believes that, if implemented, the rule could improve the drug registration and listing process. However, some elements of the proposed rule potentially have a significant negative impact upon the distribution industry. Among other things, and as discussed further below, the

proposed rule would, if made final in its present form, have important implications for the ability of pharmaceutical distributors to comply with the Prescription Drug Marketing Act (PDMA) final rule, parts of which became effective on December 1, 2006. 64 Fed. Reg. 67720 (December 3, 1999).

HDMA offers comment below on the following parts of the proposed rule:

- HDMA believes that in proposing so broad a definition of “relabel,” FDA has inadvertently reached into many common drug distributor practices and potentially significantly hampers compliance with the bar code rule and PDMA. HDMA urges FDA to exempt certain common distributor inventory control, pedigree, track-and-trace, and stickering practices from the definition of “relabel.”
- HDMA supports an Internet-enabled registration and listing process.
- HDMA supports maintenance of the current 10-digit NDC number and configuration because any change to that configuration would be enormously disruptive to industry.
- HDMA is concerned with FDA’s proposal to undertake NDC number assignment itself.
- HDMA has concerns regarding FDA’s proposal to no longer permit private label distributors to undertake registration and drug listing on their own behalf.
- HDMA believes that FDA should consider other alternatives to requiring that retail service repackaged drugs bear their own NDC number. If final, the rule would eliminate the vital retail service repackaging industry which currently adds efficiencies to the healthcare system.
- The rule, if made final as proposed, will significantly impact many common practices in healthcare distribution. For these reasons, HDMA urges the more gradual implementation timetable proposed in the rule, and asks that FDA clarify aspects of that implementation.
- HDMA urges FDA to maintain the confidentiality of information submitted for drug registration and listing.
- HDMA asks that FDA clarify the procedures for discontinuing a drug listing during the twice a year updates proposed.

- HDMA concurs with the views of others expressed at the December 11, 2006 public meeting and suggests that FDA narrow the breadth and scope of the proposed rule and approach these profound changes to the healthcare system more incrementally.

A detailed discussion of these issues is included in the attachment to this letter.

In conclusion, HDMA appreciates this opportunity to share its views with FDA and to provide our perspectives on this proposed rule. Should you have any questions about this letter, please feel free to contact Anita Ducca at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,



Anita T. Ducca
Senior Director, Regulatory Affairs
and Healthcare Policy

Attachment

Cc: Ilisa B. G. Bernstein, Pharm.D., J.D.