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**DRAFT MODEL HDMA MEMBER COMMENT LETTER
TO FDA ON THE NDC PROPOSED RULE
COMMENTS DUE JANUARY 26, 2007**

January 25, 2007

Docket Officer
Division of Dockets Management (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Room. 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. Docket No. 2005N-0403 [71 Fed. Reg. 51276, August 29, 2006]

Dear Docket Officer:

On behalf of H. D. Smith, I would like to take this opportunity to provide our comments on the 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*, 71 Fed. Reg. 51276 (Aug. 29, 2006) (the "Proposed Rule").

Before I begin, let me first introduce our company to you. Headquartered in Springfield, Illinois, H. D. Smith is the largest privately held national full-service wholesale distributor that provides a complete line of pharmaceuticals, OTCs, HBAs, surgical supplies, seasonal merchandise and a wide array of marketing programs. We are the fourth largest national pharmaceutical wholesaler servicing thousands of customers across the United States. Our company has seven distribution facilities that service major markets throughout the United States.

H. D. Smith is a member of the Healthcare Distribution Management Association ("HDMA"). As part of our membership activities, we have reviewed the HDMA written comment letter that will be submitted to the Food and Drug Administration (FDA) on the proposed rule referenced above. H. D. Smith fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.



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While we fully agree with all of the points raised in the HDMA letter, we wish to place special emphasis on the following items addressed in the HDMA comment letter regarding the proposed rule.

- We concur with the concerns HDMA raises regarding the proposed definition of the term “relabel” because it would result in redefining as “manufacturing” many common, traditional drug distributor practices. Distributors sticker and tag product to help comply with federal and state requirements and to track, control, and deliver safe, effective drug products to our customers. With changes in state law expected in the next legislative sessions, and many others that have already been enacted, we need the flexibility to be able to respond to new track, trace, and pedigree requirements that states may impose without also triggering FDA listing and registration requirements. We ask that FDA exempt common distributor inventory control, pedigree, track-and-trace, and stickering practices from the definition of “relabel.”
- We support FDA’s statement that it intends to maintain the 10-digit NDC number. It would be very burdensome and expensive for us to convert all our systems and practices to a different configuration, such as an 11-digit number. Also, those required to comply with FDA’s bar code rule if the NDC number increased beyond 10 digits.
- We do not support FDA’s proposal to assign NDC numbers itself. We also do not support FDA’s proposal to permit private label distributors to register and list on their own. We understand that FDA believes these measures are necessary to avoid confusion and incorrect drug listing. While we cannot speak to other businesses, the assignment of an NDC number is a significant and serious part of our practices and we make every effort to comply with current requirements. We do not wish to lose control over this very important part of our business.
- The rule, as proposed, has an extremely broad impact: it potentially affects all healthcare products (including drugs, devices, and dietary supplements); it changes the regulatory requirements applicable to every member of the supply chain (including manufacturers, distributors, private label distributors, and retail pharmacy); and it alters how everyone in the supply chain develops, manufactures, orders, delivers, and obtains payment and reimbursement for many of these products. Given the extent of this impact, we urge FDA to fully assess the proposed changes and move very slowly and deliberately before it changes a system that we believe is working well and efficiently to avoid disruptions to our business. We support FDA’s proposal to transfer the current, cumbersome paper-based establishment registration and drug listing process to an electronic platform and urge working with affected parties to ensure system security and compatibility. We believe FDA should concentrate its efforts on this aspect of the rule first, and then look at the other issues later after all interested stakeholders have had the opportunity to comment and FDA has had the opportunity to review that testimony.

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Thank you for this opportunity to provide our comments on the proposed rule and to endorse the comments of the HDMA as written. We hope these comments are constructive in your work to improve the registration of drug establishments and listing of drug products. If you have any questions about this letter, please feel free to contact me at (217) 467-8239 or at rlanton@hdsmith.com.

Sincerely,

Ron Lanton III

Industry Analyst
H. D. Smith