



November 7, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

Docket No. 2005N-0403 and RIN 0910-AA49

Subject: 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.

Gentlemen,

The Allergen Products Manufacturers' Association represents the allergenic extract manufacturers in science and regulatory affairs. We have been asked to respond to the proposed rule making application as referenced above wherein it has been proposed to require the NDC number to appear on the product label.

Specifically we have been asked to make our members objections to this proposed rulemaking known to the agency. Our individual members have indicated they will submit their own specific comments and reasons why they believe proposed rule will be burdensome and not fulfill some of the FDA stated initiatives.

Sincerely,  
Allergen Products Manufacturers' Association

Rebecca R. Johnson, DPh  
Vice-President

CC: Valerie A. Butler  
Center for Biologics Evaluation and Research (HFM-17)  
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