



United Research Laboratories, Inc.  
Mutual Pharmaceutical Company, Inc.

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March 29, 2004

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

Re: **Docket Number 2004P-0054**

Dear Sir or Madam:

On February 5, 2004 the undersigned submitted a Citizen Petition, which was assigned the above-referenced docket number, for the purpose of determining that the drug product Doxycycline Hyclate Capsules, 75 mg and 100 mg, was suitable for evaluation under an ANDA. This petition was believed to be necessary since the referenced product, Doryx® Capsules, was specifically listed in the Orange Book as a dosage form containing coated pellets, while the petitioner requested a dosage form not containing coated pellets.

On March 26, 2004 I was contacted by a representative of the Regulatory Support Branch, Office of Generic Drugs, and informed that a suitability petition was not necessary for the change proposed in 2004P-0054/CP1. Specifically, I was told that there was nothing in the reference product's labeling, nor was there any other reason, which would cause the reference product to be considered differently than an oral capsule dosage form. I was also specifically told that the reference product, having been listed in the Orange Book as a unique dosage form, did not make it unsuitable for referencing in an ANDA for an oral capsule product not containing coated pellets.

Consequently, on behalf of Mutual Pharmaceutical Company, I wish to withdraw my petition under Docket Number 2004P-0054.

Respectfully submitted,

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