URL MUTUAL

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

1100 Orthodox Street
Philadelphia, PA 19124
215-288-6500
www.urlmutual.com

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March 12, 2001

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

Docket Number 01P-0117

Dear Sir or Madam:

I have received your letter notifying me that my Citizen Petition was accepted for filing and was assigned the above-referenced docket number. In that letter you characterized the intent of my petition as "to rescind approval of any ANDA for a generic version of a solid oral dosage form of Metaxalone." My petition is similarly characterized on the Docket Management Branch's web page.

Please be advised that this is not an accurate representation of my petition. Specifically, my petition requests the following:

1. Rescind the previous FDA determination that Metaxalone Tablets do not pose a bioequivalence problem, and
2. Require acceptable results from an *in-vivo* fasting bioequivalence study as a condition of approval for any ANDA for a generic version of Metaxalone Tablets.

Please correct your files and your web page in order to avoid confusion as to the issues involved with this petition.

Thank you.

Sincerely,

Robert Dettery

Robert Dettery
Vice President, Regulatory Affairs
Mutual Pharmaceutical Company

01P-0117

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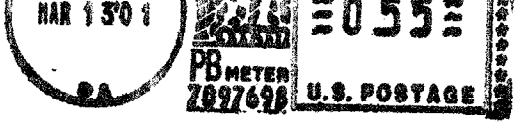

FIRST CLASS MAIL

Mutual Pharmaceutical Company
1100 Orthodox St., Philadelphia, PA 19106

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