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

1100 Orthodox Street
Philadelphia, PA 19124

215-288-6500
www.urlmutual.com

2801 '03 JUN -3 A9:30

June 2, 2003

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

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, on behalf of Mutual Pharmaceutical Company in accordance with Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.93 to request that the Commissioner of Food and Drugs permit the filing of an Abbreviated New Drug Application (ANDA) for a drug that has the same active ingredient, route of administration, and dosage strengths as a drug listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" , but differs in dosage form.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that the drug product, Propranolol HCl Extended-Release Tablets, 60 mg, 80 mg, 120 mg, and 160 mg, is suitable for evaluation under an ANDA. The referenced product is Inderal® LA Capsules, 60 mg, 80 mg, 120 mg, and 160 mg (NDA 18-553). This Petition requests a change in dosage from that of the approved extended-release oral capsule to an extended-release oral tablet.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug product that differs in dosage form from that of the listed drug provided the FDA has approved a petition that proposed filing such an application. A copy of the most recent Internet listing of the "Approved Drug Products with Therapeutic Equivalence Evaluations", included as Attachment 1, lists the reference drug, Inderal® LA Capsules, by Wyeth, Inc.

The proposed drug product is an extended-release oral tablet form, rather than an extended-release oral capsule form, in the same dosage strengths as the referenced listed drug (RLD). The proposed product contains the same active ingredient as the RLD and is intended for the same route of administration. Thus, the proposed product will be labeled with the same dosage recommendations as the RLD and is expected to have the same therapeutic effect when used as indicated in the approved labeling.

In addition, the labeling for the proposed product is expected to be substantially the same as the RLD with the exception of changes necessitated by the fact that the product is manufactured by a different company, the product is a tablet dosage form rather than a capsule dosage form, the product is referred to by the generic name Propranolol HCl Extended-Release Tablets rather than Wyeth's brand name, and the product's appearance and "How Supplied" information are different. The initial draft labeling and the approved labeling for the RLD are included as Attachments 2 and 3, respectively.

2003P-0237

CP 1

C. **Environmental Impact**

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. **Economic Impact**

Pursuant to 21 CFR 10.30(b), the economic impact information will be submitted if requested by the Agency.

E. **Certification**

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

Robert Dettery
Vice President, Regulatory Affairs
Mutual Pharmaceutical Company

Attachments:
1) electronic Orange Book listing
2) draft labeling
3) Inderal® LA Capsules labeling

Cc: G. Davis (Office of Generic Drugs)