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

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

May 16, 2003

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, in accordance with 21 CFR 10.30 requesting that the Food and Drug Administration (FDA) amend the "Approved Drug Products with Therapeutic Equivalence Evaluation" list (the "Orange Book"), 23rd edition, as outlined below.

A. Action Requested

Based on information presented herein, the petitioner requests that the FDA amend the Orange Book to designate Mutual Pharmaceutical Company's quinidine gluconate extended-release tablets as the reference listed drug. Furthermore, the petitioner requests that the designation of Mutual's product as reference listed drug replace, i.e. not be in addition to, Watson Laboratories' quinidine gluconate extended-release tablets, which was recently designated as the reference listed drug.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products approved on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act. The FDA has decided through the comment and rule making process that, for approved drug products, it will designate a reference listed drug (RLD) against which all generic versions must be shown to be bioequivalent and thus avoid possible variations among generic drugs and their brand name counterparts (57 FR 17950, 17954). For multiple source NDA drug products or multiple source drug products without an NDA, the FDA has decided to generally designate the market leader as the reference listed drug.

With regards to quinidine gluconate extended-release tablets, until recently the designated RLD was Berlex Laboratories' Quinaglute® Tablets. However, according to FDA's electronic version of the Orange Book, Berlex has discontinued marketing of this product and has withdrawn their NDA, presumably for reasons other than safety or ineffectiveness. The withdrawal of Berlex's NDA, and subsequent transfer of their Orange Book listing to the Discontinued Drug Product List section, left Watson and Mutual as the only holders of approved applications for quinidine gluconate extended-release tablets. Again, according to FDA's electronic version of the Orange Book, the agency designated Watson's product as the new RLD, to replace Quinaglute® Tablets, and displayed a therapeutic equivalence code rating of "BX" for Mutual's product.

The petitioner believes this was an erroneous action on the agency's part for the following reasons:

1. Mutual Pharmaceutical Company is clearly the market leader for quinidine gluconate extended-release tablets. Based on marketing data for the calendar year 2002, Mutual had 58% of the total market and 73% of the generic market for quinidine gluconate extended-release tablets. When combined with the sales for United Research Laboratories, an own-label distributor that is related to Mutual, this market share increases to 70% of the total market and 87% of the generic market. During the same time period, Watson's market share was 10% and 13%, respectively.

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2. On June 14, 2002 Mutual Pharmaceutical Company submitted bioequivalence data to FDA's Office of Generic Drugs, Division of Bioequivalence, which demonstrated bioequivalence between Mutual's product and Berlex's Quinaglute® Tablets. At that time, Quinaglute® Tablets was the RLD and both Watson's and Mutual's products were designated with the therapeutic equivalence code "BX", meaning bioequivalence had not been established. On March 31, 2003 Mutual's supplemental application containing that bioequivalence data was approved by the agency, but before the therapeutic equivalence code for Mutual's quinidine gluconate extended-release tablets could be revised from "BX" to "AB", Quinaglute® was removed from the Prescription Drug Product List section of the Orange Book.

   Consequently, the Orange Book listing for Watson's quinidine gluconate extended-release tablets presently has no therapeutic equivalence rating code, while the listing for Mutual's quinidine gluconate extended-release tablets retains the "BX" code. Not only does the "BX" rating infer a negative connotation and adversely effects the acceptance of Mutual's product in some state formularies, the designation of "BX" is patently unfair considering that Mutual's product (and to the best of the petitioner's knowledge, not Watson's) was proven bioequivalent to the original RLD, Quinaglute®.

3. The petitioner believes that Watson Laboratories has currently discontinued the marketing of their quinidine gluconate extended-release tablets. Accompanying this petition is a copy of Watson's "Product Deletion Notification", dated November 5, 2002, stating that this product was being discontinued. Furthermore, a present-day search of Watson's web site revealed that quinidine gluconate extended-release tablets is not currently included on that company's product list.

For the reasons stated above, the petitioner believes the Action Requested is justified and would rectify an incorrect action by the agency.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

Mutual does not believe that this is applicable in this case, but will agree to provide such an analysis, 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

Cc: G. Davis (Office of Generic Drugs)
C. Parise (Office of Generic Drugs)
D. Hare (Office of Generic Drugs)

INFO-LERT

Product Deletion Notification

November 5, 2002

Effective immediately, all strengths and sizes of Quinidine Gluconate 324mg ER tablets will be discontinued. All backorders will be canceled. Third Party Agencies have been notified of the discontinuation and the product should remain active for reimbursement until expiration.

NDC	Product	Strength	Size
00591-5538-01	Quinidine Gluc ER	324mg	100
00591-5538-25	Quinidine Gluc ER	324mg	250
00591-5538-05	Quinidine Gluc ER	324mg	500

Should you have questions, contact our Customer Service Department at 800-272-5525.

Thank you for your continued support of Watson products.

WATSON Laboratories, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc.