DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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AUG 31 2001

Mr. Robert Dettery
Vice President, Regulatory Affairs
Mutual Pharmaceutical Company
1100 Orthodox Street
Philadelphia, PA 19124

Docket No. 01P-0117/CP1

Dear Mr. Dettery:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated March 6, 2001, asking that the Agency reclassify metaxalone tablets (brand name Skelaxin) as a drug product with potential or actual bioequivalence problems and make inclusion of an *in vivo* fasting bioequivalence study a condition of approval for an abbreviated new drug application (ANDA) for metaxalone tablets.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0117

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