



01P-0481 (02-03-02) 000

March 11, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket #01P-0481 (Citizen Petition Submitted by Elan Pharmaceuticals)

Dear Sir/Madam:

Kali Laboratories, Inc. would like to comment on the Citizen Petition (Docket #01P-0481) submitted by Elan Pharmaceuticals concerning the bioequivalence requirements for a generic version of Skelaxin® (metaxalone) tablets, 400 mg. Specifically, the requirement for a food effect bioequivalence study as a condition for ANDA approval of a generic metaxalone tablet, 400 mg is unwarranted.

Metaxalone (Skelaxin®) tablets have been marketed in the US for 38 years and have been used by hundreds of millions of patients without any regard for food. Labeling for metaxalone tablets does not contain any information regarding food. According to the manufacturer, the recommended Skelaxin® dosage for adults and children over 12 years of age is two tablets (800 mg) three to four times a day.¹ This frequent dosage schedule of two tablets (800 mg) given three to four times a day implies that patients may take metaxalone at times before or after a meal without any clinical consequence.

The total daily dose for metaxalone ranges from 2400 mg to 3200 mg. This large daily dosage also shows that small fluctuations in blood levels would not be of clinical importance. At steady-state, any fluctuation in plasma drug concentrations due to food would not be observed.

Kali Laboratories, Inc. strongly feels that the long history of metaxalone in the marketplace attests to the efficacy and safety of this drug. There is no safety concern for requiring additional food-effect bioequivalence studies for a generic version of metaxalone tablets, 400 mg, especially for a drug that is taken three to four times a day with total daily dosage up to 3200 mg per day.

We appreciate your consideration of our request and look forward to your quick-resolution on this important issue, so that the American consumer may avail himself another cost effective medicine. We hope that our comments are clear and welcome any questions that you may have.

Sincerely,

Veerappan S. Subramanian, Ph.D.
President & CEO

¹Physicians' Desk Reference, Vol 56, 2002, p.1301

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01P-0481

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