DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 15 2003

Gary L. Yingling
Counsel for Mechanical Servants
Kirkpatrick & Lockhart, LLP
1800 Massachusetts Avenue, NW
Suite 200
Washington, DC 20036-1221

Re: Docket No. 02P-0446/CP1

Dear Mr. Yingling:

This letter is in reference to your citizen petition (CP1), on behalf of your client, Mechanical Servants, Inc., dated October 9, 2002. This document is filed under Docket No. 02R-0446 in the Dockets Management Branch. The petition requests the Commissioner to set forth, through implementation of a guidance or policy statement, the "inner package" labeling requirements for most convenience size drug products where fully compliant labeling appears on the outer container of the retail package. The petition also requests the Commissioner to implement a regulation that acknowledges and accepts a "reverse guaranty" as a basis for exemption from certain liabilities under the Federal Food, Drug, and Cosmetic Act.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. [See 21 CFR 10.30(e)]. This letter is to advise you, pursuant to 21 CFR 10.30(e)(2), that the petition is still being reviewed, and the agency is unable to provide a response to the petition at this time.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

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

02P-0446

LET 1