DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 8 2003

Mr. Carlos T. Angulo
Zuckerman Spaeder LLP
1201 Connecticut Avenue, N.W.
Washington, D.C. 20036

Docket No. 02P-0493/CP1

Dear Mr. Angulo:

This letter responds to your citizen petition dated November 20, 2002, submitted on behalf of Andrx Pharmaceutical Corp., requesting that FDA deny Proctor & Gamble/Astra Zeneca's new drug application seeking approval for over-the-counter use of Prilosec (omeprazole magnesium).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible, given the numerous demands on the Agency's resources.

Sincerely yours,

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

02P0493 LET 1