

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11821



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

JUN 03 1975

Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
Select Committee on Small Business
United States Senate
Washington, D.C. 20510

Dear Senator Nelson:

Thank you for your letter of March 3, 1975, requesting our comments on interoffice memoranda of Abbott Laboratories concerning bioavailability studies conducted by The Upjohn Company comparing their E-Mycin (erythromycin base) with Abbott Laboratories Erythrocin Stearate Filmtab (erythromycin stearate).

These memoranda make several valid points, and, in particular, they point out that comparing the bioavailability of drugs which are not generic equivalents may not be appropriate. Such drugs should not necessarily be expected to be comparable under all conditions of use, although when used as labeled they should be expected to provide comparable effectiveness.

It is important to note that the Upjohn studies referred to in the Abbott memoranda compared erythromycin base with erythromycin stearate. While both products contained the same active chemical moiety (erythromycin), they were not generic equivalents, i.e., not chemically identical. In this instance the chemical variation introduced differences in the bio-pharmaceutical properties of the products. Specifically, as is noted, the oral erythromycin base as compared with the erythromycin stearate provides higher erythromycin serum levels when administered in the presence of food.

The labeling of Abbott Laboratories' erythromycin stearate recognizes the effect of food on their product by stating, "Optimum blood levels are obtained when doses are given on an empty stomach."

Interestingly, Abbott's interoffice correspondence includes a study comparing their erythromycin base with Upjohn's enteric coated erythromycin base. This too results in a study comparing two nonequivalent products due to the fact the enteric control product has been specifically formulated to prevent absorption of the active drug ingredient until it passes the stomach, whereas the nonenteric coated Abbott product begins to be absorbed earlier, while still in the stomach.