In your letter you ask for our comments as to whether the material from the Abbott Laboratories may be relevant to other studies conducted in the field. Our experience to date indicates that such situations and disputes are not common. Under our generic drug policy, generic products must be equivalent to the product of the original holder (innovator) of the new drug application (NDA). Subsequent generic manufacturers must provide a product which is neither significantly higher nor lower in product performance than the innovator's product, as shown by comparative drug serum levels. The situation with the erythromycins is unusual in that for the same active moiety, erythromycin, there are several innovator products, e.g., erythromycin stearate, base, estolate, etc.

We have seen various E-Mycin promotional materials, submitted in 1973 and 1974 pursuant to 21 CFR 430.60(b)(3), Records and Reports Concerning Experience with Antibiotic Drugs, in which comparative products are not identified by brand name or company; in these cases the differences in indicated administration were clearly stated.

We have also seen an Upjohn booklet titled "Basics of Bioavailability and Description of Upjohn Single-dose Study Design * * *." This booklet (G-3260-9 October 1973), authored by D.J. Chodos, M.D., and A.R. DiSanto, Ph.D., deals primarily with Upjohn penicillin products and does not name competitive brands in the illustrated studies, using "Treatment A" and "Treatment B," etc., instead. It is not regarded as violative under existing laws and regulations. We are not aware of any other similar Upjohn product promotional material.

We have taken regulatory action in the past when various manufacturers have attempted to imply clinical superiority by presentation of serum or other tissue level data that did not constitute substantial evidence of real clinical advantage. We will not hesitate to take future actions along these same lines when improper bioavailability claims are made.

Sincerely yours,

A. M. Schmidt

Alexander M. Schmidt, M.D.
Commissioner of Food and Drugs

Enclosure