EXHIBIT C

APhA Newsletter

Latiolais criticizes Proprietary Association's views on antacid monograph

APhA President Clifton J. Latiolais has branded as "entirely self-serving" a recent statement by the Proprietary Association challenging a Food and Drug Administration labeling proposal. The FDA recommendation would require labels of charcoal-containing antacid products to indicate that the products are not to be used "concurrently with a prescription drug except on the advice of your physician or pharmacist."

The PA statement, filed with FDA on June 4 in response to a *Federal Register* proposal to establish a monograph on o-t-c antacid products, attempted to minimize the importance of potential drug interactions "that are more theoretical in nature than of demonstrable significance."

"APhA does indeed recognize that not all reported drug interactions are clinically significant," President Latiolais stated. "This is the reason the Association undertook the project which resulted in the publication, *Evaluations of Drug Interactions—1973*. However, the fact that some interactions are theoretical and suspect at present due to inadequate documentation in no way decreases the need to guard the patient against those interactions that have been proven to be clinically significant. To categorize these potentially significant drug therapy problems with less important ones, and then to suggest that the medicating public not be apprised of a knowledgeable source of information is clearly not in the best interest of the self-medicating public."

The PA statement also questioned "whether the pharmacist has the time, expertise or inclination to provide this information to the consumer."

"To question the expertise of a health professional with five or six years of extensive training in drugs and drug therapy is completely ludicrous," President Latiolais declared. "Further, it is ironical that many of those pharmacists who do not have time to coun-

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Contact IRS for information on the price freeze

The Cost of Living Council reports that "economic stabilization information" is available by phone from 58 district Internal Revenue Service offices across the country. Those pharmacists who wish to contact the Council should write Cost of Living Council, 2000 M St., N.W., Washington, D.C. 20508. The IRS, which has been a part of the economic stabilization plan, will answer questions and receive complaints. During the price freeze, ordered by President Nixon June 13 for a maximum of 60 days, services or products may not be available or sold at fees or prices above the highest charges or prices at which they were available during the previous June 1-8.

Commentary on digoxin bioavailability by Colaizzi

An April 9 editorial and an April 9 article in the Journal of the American Medical Association have caused pharmacists to be concerned about the bioavailability of digoxin tablets they dispense. The following commentary on the subject was prepared for the APhA Newsletter by John L. Colaizzi, Ph.D., Director of the APhA Bioavailability Pilot Project.

Digoxin is a widely utilized drug which possesses life-saving characteristics. Precise dosage regulation is particularly essential with digoxin and other digitalis derivatives due to the narrow margin between ineffective doses and therapeutic doses, and again between therapeutic and toxic doses. For these reasons, the U.S.P. has specified a content uniformity test for digoxin tablets; this requirement is designed to ensure uniform tablet-to-tablet potency within individual lots of the drug product.

Moreover, the Food and Drug Administration developed a voluntary certification program for digoxin tablets through which manufacturers voluntarily submit samples from each batch to FDA for content uniformity and other U.S.P. tests prior to releasing the batch on the market. In October, 1971, FDA's National Center for Drug Analysis reported that 47 percent of the batches investigated did not comply with the U.S.P. monograph requirements, chiefly because of failure in the content uniformity test.[1] FDA's monitoring efforts since 1971 have virtually ensured that digoxin tablets reaching pharmacists' shelves meet all U.S.P. specifications.

Moreover, the study by Lindenbaum *et al*[2], which reported significant differences in the biological availability of three different brands of digoxin tablets based on serum level determinations in human subjects, understandably caused concern among the medical and pharmaceutical professions when it appeared in December of 1971. Not only did this study reveal wide variations in serum levels obtained with the different brands of tablets, but also with different lots of tablets of the same brand. Following publication of this work, a number of deficiencies in the study were pointed out.[3, 4] For example, at least one of the lots of tablets studied by Lindenbaum *et al* was found to

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