

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10679

subject to regulatory procedures under section 505 of the act.

The Commissioner has determined that, in view of the questions raised regarding the bioavailability of digoxin products for oral use, there is sufficient evidence to invoke the authority under section 505(j) of the act to fully investigate this question in order to obtain more definitive data to demonstrate the bioavailability of these products and to correlate bioavailability in vivo with the dissolution rate of digoxin tablets in vitro. Therefore, any person who submits an abbreviated new drug application for digoxin products for oral use shall, within the times specified in the new § 130.51, submit to the Food and Drug Administration additional data in the form of records and reports, pursuant to section 505(j) of the act, which show adequate evidence of the product's bioavailability. A review of these data will facilitate a determination of whether there is a ground for withdrawing approval of the drug in question under section 505(e) of the act. Failure to submit these required records and reports is in itself a violation of the act, justifying withdrawal of approval of the application.

Digoxin products for parenteral use are new drugs subject to the requirements of the Drug Efficacy Study Implementation notice (DESI 8627) published in the FEDERAL REGISTER of July 27, 1972 (37 FR 15024). The conditions for marketing digoxin products for parenteral use are described in the DESI notice and include a requirement for the submission of data to show the biologic availability of the drug in the formulation which is marketed.

Digoxin tablets formulated so that the quantity of digoxin dissolved