product to achieve dissolution of 70 to 90 percent at one hour when tested by all three methods (i.e., the USP method, and the "paddle-water" and "paddle-acid" methods) described in paragraph (h) of this section.

(d) The protocol for the in vivo bioavailability tests required in paragraphs (a) and (c) of this section shall employ a three-way crossover design using the digoxin test product; a reference digoxin tablet supplied, on request, by the Food and Drug Administration; and bulk digoxin USP in an oral solution. Appropriate venous blood and urinary samples are to be collected and analyzed. The method shall be capable of detecting the difference between the reference tablet and the reference oral solution. Bioavailability of the test product shall be demonstrated if a mean absorption of at least 75 percent of the combined mean of the two reference standards is observed. Assistance in developing a protocol for a particular dosage formulation may be obtained by contacting the Food and Drug Administration, Bureau of Drugs (HFD-220), 5600 Fishers Lane, Rockville, MD 20852.

(e) Parts of the digoxin product labeling indicated below shall be substantially as follows:

CARDIAC (DIGITALIS) GLYCOSIDES LABELING
GUIDELINE (ADULT)

DESCRIPTION

The cardiac (or digitalis) glycosides are a closely related group of drugs having in common specific and powerful effects on the myocardium. These drugs are found in a number of plants. The term "digitalis" is used to designate the whole