(f) Abbreviated new drug applications shall be submitted to the Food and Drug Administration, Bureau of Drugs, Office of Scientific Evaluation, Generic Drug Staff (HFD-107), 5600 Fishers Lane, Rockville, MD 20852.

(g) All samples of digoxin tablets required by paragraph (a)(3) of this section to be submitted to the Food and Drug Administration shall be handled as follows:

(1) The sample shall consist of 6 subsamples of 1000 tablets each collected at random from throughout the manufacturing run. Each of the 6 subsamples shall be identified with the name of the product, the labeled potency, the date of manufacture, the batch number, and the name and address of the manufacturer.

(2) The sample together with the batch production record and results of all tests conducted by or for the manufacturer to determine the product's identity, strength, quality, and purity, content uniformity and dissolution shall be submitted to the Department of Health, Education, and Welfare, Public Health Service, FDA National Center for Drug Analysis, 1114 Market St., St Louis, MO 63101. The outer wrapper shall be identified "SAMPLE -- DIGOXIN CERTIFICATION."

(h) The Food and Drug Administration is aware of data with two in vitro methods, in addition to that described in The United States Pharmacopeia (USP XVIII), developed to measure digoxin tablets dissolution.