Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 501(b), 502, 505, 701(a); 52 Stat. 1041-1042, 1049-1053, 1055; 21 U.S.C. 321(p), 351(b), 352, 355, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), Part 130 of Title 21 of the Code of Federal Regulations is amended by adding a new § 130.51 as follows:

§ 130.51 Digoxin products for oral use; conditions for marketing.

(a) Studies have shown evidence of clinically significant differences in bioavailability in different batches of certain marketed digoxin products for oral use from single manufacturers as well as in batches of these products produced by different manufacturers. These differences were observed despite the fact that the products met compendial specifications. Other studies have shown that there is a sufficient correlation between bioavailability in vivo and the dissolution rate of digoxin tablets in vitro to make the dissolution test an important addition to the compendial standards. Because of the potential for serious risk to cardiac patients using digoxin products which may vary in bioavailability, the Commissioner of Food and Drugs has determined that immediate action must be taken to assure the uniformity of all digoxin products for oral use. The Commissioner is of the opinion that digoxin products for oral use are new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act for which approved new drug applications are required. The Commissioner has determined that, because of questions raised regarding the bioavailability of digoxin products for oral use, there is sufficient evidence to invoke