U.S. Code of Federal Regulations

U.S. Code of Federal Regulations
TITLE 21 C.F.R. [Food and Drugs]
CHAPTER I FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H MEDICAL DEVICES
PART 812 INVESTIGATIONAL DEVICE EXEMPTIONS
Subpart A General Provisions

[Previous Document in Book] [Next Document in Book]

21 C.F.R. § 812.7 **Prohibition of promotion and other practices.**

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.

(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.

(c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.

(d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

[Previous Document in Book] [Next Document in Book]