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 ADMINISTRATIO	N, DEPARTMENT OF HEALTH AND
HUMAN SERVICES	
SUBCHAPTER H MEDICAL DEVICES	
PART 812 INVESTIGATIONAL DEVICE EXEMPT	IONS
Subpart A General Provisions	
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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 for 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.

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