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Regulatory Application Sponsor

National Cancer Institute

Source

National Cancer Institute. *Regulatory Application Sponsor*. NCI Thesaurus. Code C71136.

The party who submits a marketing application to FDA for approval of a drug, device, or biologic product. An applicant is the person or entity who assumes responsibility for the marketing of a new medical product, including responsibility for compliance with applicable provisions of the Federal Food, Drug, and Cosmetic Act and related regulations. The sponsor is usually an individual, partnership, corporation, government agency, manufacturer or scientific institution.