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505(b)(2) New Drug Application

National Cancer Institute

Source

National Cancer Institute. *505(b)(2) New Drug Application*. NCI Thesaurus. Code C72905.

A new drug application submitted under section 505(b)(1) of the CFR Title 21, Chapter 9 (FEDERAL FOOD, DRUG, AND COSMETIC ACT) for a drug for which the investigations described in section 505(b)(1)(A) of the act and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. An applicant should submit a 505(b)(2) application if approval of an application will rely to any extent on published literature, or on the Agency's previous finding of safety and/or effectiveness for a drug.