Food and Drug Administration, HHS

§ 50.3 Definitions.

As used in this part:
(b) Application for research or marketing permit includes:
(1) A color additive petition, described in part 71.
(2) A food additive petition, described in parts 171 and 571.
(3) An investigational new drug application, described in part 312 of this chapter.
(4) Data and information about a food additive submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§170.30 and 570.30.
(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.
(6) An investigational new drug application, described in part 312 of this chapter.
(7) A new drug application, described in part 314.
(8) Data and information about the bioavailability or bioequivalence of drugs for human use submitted as part