

§ 26.81 Final provisions.

(a) The sectoral annexes referred to in § 26.80(a), as well as any new sectoral annexes added pursuant to § 26.80(b), shall form an integral part of the "Agreement on Mutual Recognition Between the United States of America and the European Community," from which this part is derived.

(b) For a given product or sector, the provisions contained in subparts A and B of this part shall apply in the first place, and the provisions of subpart C of this part in addition to those provisions. In the case of any inconsistency between the provisions of subpart A or B of this part and subpart C of this part, subpart A or B shall prevail, to the extent of that inconsistency.

(c) The agreement from which this part is derived shall not affect the rights and obligations of the parties under any other international agreement.

(d) In the case of subpart B of this part, the parties shall review the status of such subpart at the end of 3 years from the date described in § 26.80(a).

PART 50—PROTECTION OF HUMAN SUBJECTS**Subpart A—General Provisions**

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AUTHORITY: 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 45 FR 36390, May 30, 1980, unless otherwise noted.

Subpart A—General Provisions**§ 50.1 Scope.**

(a) This part applies to all clinical investigations regulated by the Food and

Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 406, 409, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[45 FR 36390, May 30, 1980; 46 FR 8979, Jan. 27, 1981, as amended at 63 FR 26697, May 13, 1998; 64 FR 399, Jan. 5, 1999]

§ 50.3 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 321–392)).

(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) Data and information about a substance 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.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be