

Food and Drug Administration, HHS

§ 99.3

99.405 Applicability of labeling, adulteration, and misbranding authority.

Subpart F—Recordkeeping and Reports

99.501 Recordkeeping and reports.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360c, 360e, 360aa–360aaa–6, 371, and 374; 42 U.S.C. 262.

SOURCE: 63 FR 64581, Nov. 20, 1998, unless otherwise noted.

Subpart A—General Information

§ 99.1 Scope.

(a) This part applies to the dissemination of information on human drugs, including biologics, and devices where the information to be disseminated:

(1) Concerns the safety, effectiveness, or benefit of a use that is not included in the approved labeling for a drug or device approved by the Food and Drug Administration for marketing or in the statement of intended use for a device cleared by the Food and Drug Administration for marketing; and

(2) Will be disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency.

(b) This part does not apply to a manufacturer's dissemination of information that responds to a health care practitioner's unsolicited request.

§ 99.3 Definitions.

(a) *Agency* or *FDA* means the Food and Drug Administration.

(b) For purposes of this part, a *clinical investigation* is an investigation in humans that tests a specific clinical hypothesis.

(c) *Group health plan* means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(1))) to the extent that the plan provides medical care (as defined in paragraphs (c)(1) through (c)(3) of this section and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. For purposes of this part, the term *medical care* means:

(1) Amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;

(2) Amounts paid for transportation primarily for and essential to medical care referred to in paragraph (c)(1) of this section; and

(3) Amounts paid for insurance covering medical care referred to in paragraphs (c)(1) and (c)(2) of this section.

(d) *Health care practitioner* means a physician or other individual who is a health care provider and licensed under State law to prescribe drugs or devices.

(e) *Health insurance issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (e)(2) of this section) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)(2))).

(1) Such term does not include a group health plan.

(2) For purposes of this part, the term *health maintenance organization* means:

(i) A Federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a)));

(ii) An organization recognized under State law as a health maintenance organization; or

(iii) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(f) *Manufacturer* means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. For purposes of this part, the term may also include the sponsor of the approved, licensed, or cleared drug or device.

(g) *New use* means a use that is not included in the approved labeling of an approved drug or device, or a use that is not included in the statement of intended use for a cleared device.