

externally applied drugs and cosmetics after July 15, 1988, and use of these color additives in the manufacture of ingested drugs and cosmetic lip products and in externally applied drugs and cosmetics after this date will result in adulteration.

(4) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drug and cosmetic lip products and externally applied drugs and cosmetics to which the color additives were added on or before July 15, 1988.

(t)(1) Certificates issued for D&C Orange No. 17, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in ingested drugs and ingested cosmetics after March 31, 1983 and use of this color additive in the manufacture of ingested drugs or ingested cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additive was added on or before March 31, 1983.

(3) Certificates issued for D&C Orange No. 17, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Orange No. 17 was added on or before July 15, 1988.

(u)(1) Certificates issued for FD&C Red No. 3 and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in cosmetics and externally applied drugs after January 29, 1990. Certificates issued for FD&C Red No. 3 lakes and all mixtures containing these lakes are cancelled and have no effect as pertains to their use in food, drugs, and cosmetics after January 29, 1990. Certificates issued for D&C Red No. 3 lakes and all mixtures containing those

lakes are cancelled and have no effect as pertains to their use in drugs and cosmetics after January 29, 1990. Use of this color additive in the manufacture of cosmetics and of externally applied drugs and any use of the lakes of FD&C Red No. 3 (including the lakes of D&C Red No. 3) after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action must be taken to remove from the market food, drugs, and cosmetics to which the provisionally listed color additive or its lakes were added on or before January 29, 1990.

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §81.30, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

## PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

### Subpart A—General Provisions

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- 82.3 Definitions.
- 82.5 General specifications for straight colors.
- 82.6 Certifiable mixtures.

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- 82.50 General.
- 82.51 Lakes (FD&C).
- 82.101 FD&C Blue No. 1.
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- 82.706 FD&C Yellow No. 6.

### Subpart C—Drugs and Cosmetics

- 82.1050 General.
- 82.1051 Lakes (D&C).
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- 82.1260 D&C Orange No. 10.
- 82.1261 D&C Orange No. 11.
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- 82.1317 D&C Red No. 17.
- 82.1321 D&C Red No. 21.
- 82.1322 D&C Red No. 22.
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82.1328 D&C Red No. 28.  
82.1330 D&C Red No. 30.  
82.1331 D&C Red No. 31.  
82.1333 D&C Red No. 33.  
82.1334 D&C Red No. 34.  
82.1336 D&C Red No. 36.  
82.1602 D&C Violet No. 2.  
82.1707 D&C Yellow No. 7.  
82.1708 D&C Yellow No. 8.  
82.1710 D&C Yellow No. 10.

### Subpart D—Externally Applied Drugs and Cosmetics

82.2050 General.  
82.2051 Lakes (Ext. D&C).  
82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

### Subpart A—General Provisions

#### § 82.3 Definitions.

For the purposes of this part:

(a)–(f) [Reserved]

(g) The term *alumina* means a suspension in water of precipitated aluminum hydroxide.

(h) The term *blanc fixe* means a suspension in water of precipitated barium sulfate.

(i) The term *gloss white* means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term *mixed oxides* means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term *externally applied drugs and cosmetics* means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)–(p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

#### § 82.5 General specifications for straight colors.

No batch of a straight color listed in subpart B, C, or D shall be certified under this part unless:

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(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in subpart B:

(i) Lead (as Pb), not more than 0.001 percent.

(ii) Arsenic (as  $As_2O_3$ ), not more than 0.00014 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in subpart C or D:

(i) Lead (as Pb), not more than 0.002 percent.

(ii) Arsenic (as  $As_2O_3$ ), not more than 0.0002 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in subpart C or D—soluble barium (in dilute HCl) (as  $BaCl_2$ ), not more than 0.05 percent.

#### § 82.6 Certifiable mixtures.

(a) A batch of a mixture which contains no straight color listed in subpart C or D may be certified for use in food, drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than  $\frac{1}{10}$  of 1 percent) in such mixture is a nonnutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with

§80.21 of this chapter, and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in subpart D, or which contains a diluent not permitted by paragraph (a)(3) of this section, may be certified in accordance with the provisions of this part, for use only in drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in subpart D may be certified in accordance with the provisions of this part, for use only in externally applied drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

### Subpart B—Foods, Drugs, and Cosmetics

#### § 82.50 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of the regulations in this part, for use in food, drugs, and cosmetics, if such batch conforms to the requirements of §82.5 and to the specifications in this subpart set forth for such color.

#### § 82.51 Lakes (FD&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, a salt prepared from one of the certified water-soluble straight colors hereinbefore listed in this subpart by com-

binning such color with the basic radical aluminum or calcium.

(2) *Specifications.* Prepared from previously certified colors listed in this subpart.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble HCl, not more than 0.5 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word "Lake".

(For example, the name of a lake prepared by extending the aluminum salt prepared from FD&C Blue No. 1 upon the substratum would be FD&C Blue No. 1—Aluminum Lake.)

#### § 82.101 FD&C Blue No. 1.

The color additive FD&C Blue No. 1 shall conform in identity and specifications to the requirements of §74.101(a)(1) and (b) of this chapter.

#### § 82.102 FD&C Blue No. 2.

The color additive FD&C Blue No. 2 shall conform in identity and specifications to the requirements of §74.102(a)(1) and (b) of this chapter.

[48 FR 5261, Feb. 4, 1983]

#### § 82.203 FD&C Green No. 3.

The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of §74.203(a)(1) and (b) of this chapter.

[47 FR 52144, Nov. 19, 1982]

#### § 82.304 FD&C Red No. 4.

The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of §74.1304(a)(1) and (b) of this chapter. FD&C Red No. 4 is restricted to use in externally applied drugs and cosmetics.

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### § 82.705 FD&C Yellow No. 5.

The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b) of this chapter.

[51 FR 24519, July 7, 1986]

### § 82.706 FD&C Yellow No. 6.

(a) The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b) of this chapter.

(b) All lakes including current D&C external and D&C lakes of FD&C Yellow No. 6 shall be manufactured from previously certified batches of the straight color additive.

[52 FR 21509, June 8, 1987]

## Subpart C—Drugs and Cosmetics

### § 82.1050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use only in drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

### § 82.1051 Lakes (D&C).

(a)(1) *General.* Any lake, other than those listed in subpart B, made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of two or more of these, (i) one of the straight colors (except lakes) listed in subpart B or hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium; or (ii) a salt prepared from one of the straight colors (except lakes) listed in subpart B, or hereinbefore listed in this subpart, by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.  
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.  
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared, except that if such name contains the symbol “FD&C” such symbol shall be changed to “D&C”;

(2) The name of the basic radical combined in such color; and

(3) The word ‘Lake.’

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is ‘D&C Red No. 9—Barium Lake’, and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is ‘D&C Green No. 1—Aluminum Lake’.)

### § 82.1104 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b) of this chapter. D&C Blue No. 4 is restricted to use in externally applied drugs and cosmetics.

### § 82.1205 D&C Green No. 5.

The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205(a)(1) and (b)(2) of this chapter.

[47 FR 24285, June 4, 1982]

### § 82.1206 D&C Green No. 6.

The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b) of this chapter. D&C Green No. 6 is restricted to use in externally applied drugs and cosmetics.

[47 FR 14147, Apr. 2, 1982, as amended at 51 FR 9785, Mar. 21, 1986]

### § 82.1254 D&C Orange No. 4.

The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254(a)(1) and (b) of this chapter. D&C Orange No. 4 is restricted to use in externally applied drugs and cosmetics.

[42 FR 52396, Sept. 30, 1977]

**§ 82.1255 D&C Orange No. 5.**

(a) The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255(a)(1) and (b) of this chapter. D&C Orange No. 5 is restricted to the uses described in this section.

(b) The color additive D&C Orange No. 5 may be safely used for coloring externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug. The color additive D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products, and for coloring mouthwashes, dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

[49 FR 13343, Apr. 4, 1984]

**§ 82.1260 D&C Orange No. 10.**

The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements to § 74.1260(a)(1) and (b) of this chapter. D&C Orange No. 10 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

**§ 82.1261 D&C Orange No. 11.**

The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b) of this chapter. D&C Orange No. 11 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

**§ 82.1306 D&C Red No. 6.**

(a) The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

**§ 82.1307 D&C Red No. 7.**

(a) The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

**§ 82.1317 D&C Red No. 17.**

The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317 (a)(1) and (b) of this chapter. D&C Red No. 17 is restricted to use in externally applied drugs and cosmetics.

**§ 82.1321 D&C Red No. 21.**

The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321 (a)(1) and (b) of this chapter.

[47 FR 53847, Nov. 30, 1982]

**§ 82.1322 D&C Red No. 22.**

The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322 (a)(1) and (b) of this chapter.

[47 FR 53847, Nov. 30, 1982]

**§ 82.1327 D&C Red No. 27.**

The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of § 74.1327 (a)(1) and (b) of this chapter.

[47 FR 42568, Sept. 28, 1982]

**§ 82.1328 D&C Red No. 28.**

The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b) of this chapter.

[47 FR 42568, Sept. 28, 1982]

**§ 82.1330 D&C Red No. 30.**

The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b) of this chapter.

[47 FR 22511, May 25, 1982]

**§ 82.1331**

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**§ 82.1331 D&C Red No. 31.**

The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b) of this chapter. D&C Red No. 31 is restricted to use in externally applied drugs and cosmetics.

**§ 82.1333 D&C Red No. 33.**

(a) The color additive D&C Red No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b) of this chapter.

(b) All lakes of D&C Red No. 33 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 33121, Aug. 30, 1988]

**§ 82.1334 D&C Red No. 34.**

Calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azol-2-naphthalenecarboxylic acid.

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.

Subsidiary colors, not more than 4 percent.

Total color not less than 85 percent.

**§ 82.1336 D&C Red No. 36.**

(a) The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b) of this chapter.

(b) All lakes of D&C Red No. 36 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 29031, Aug. 2, 1988]

**§ 82.1602 D&C Violet No. 2.**

The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b) of this chapter.

**§ 82.1707 D&C Yellow No. 7.**

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

**§ 82.1708 D&C Yellow No. 8.**

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.

**§ 82.1710 D&C Yellow No. 10.**

The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b) of this chapter.

[48 FR 39220, Aug. 30, 1983]

**Subpart D—Externally Applied  
Drugs and Cosmetics**

**§ 82.2050 General.**

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

**§ 82.2051 Lakes (Ext. D&C).**

(a)(1) *General.* Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, barium, or calcium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.  
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.  
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

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(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word "Lake." (For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is "Ext. D&C Yellow No. 2—Calcium Lake," and a lake prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is "Ext. D&C Red No. 2—Barium Lake.")

### § 82.2707a Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of § 74.1707a(a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

## PARTS 83–98 [RESERVED]

## PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

### Subpart A—General Information

Sec.

99.1 Scope.

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### Subpart B—Information To Be Disseminated

99.101 Information that may be disseminated.

99.103 Mandatory statements and information.

99.105 Recipients of information.

### Subpart C—Manufacturer's Submissions, Requests, and Applications

99.201 Manufacturer's submission to the agency.

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99.301 Agency action on a submission.

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### Subpart E—Corrective Actions and Cessation of Dissemination

99.401 Corrective actions and cessation of dissemination of information.

99.403 Termination of approvals of applications for exemption.

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