

Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act

§ 2.125 Use of ozone-depleting substances in foods, drugs, devices, or cosmetics.

(a) As used in this section, *ozone-depleting substance* (ODS) means any class I substance as defined in 40 CFR part 82, appendix A to subpart A, or class II substance as defined in 40 CFR part 82, appendix B to subpart A.

(b) Except as provided in paragraph (c) of this section, any food, drug, device, or cosmetic that is, consists in part of, or is contained in an aerosol product or other pressurized dispenser that releases an ODS is not an essential use of the ODS under the Clean Air Act.

(c) A food, drug, device, or cosmetic that is, consists in part of, or is contained in an aerosol product or other pressurized dispenser that releases an ODS is an essential use of the ODS under the Clean Air Act if paragraph (e) of this section specifies the use of that product as essential. For drugs, including biologics and animal drugs, and for devices, an investigational application or an approved marketing application must be in effect, as applicable.

(d) [Reserved]

(e) The use of ODSs in the following products is essential:

(1) *Metered-dose corticosteroid human drugs for oral inhalation*. Oral pressurized metered-dose inhalers containing the following active moieties:

- (i)–(ii) [Reserved]
- (iii) Flunisolide.
- (iv) [Reserved]
- (v) Triamcinolone.

(2) *Metered-dose short-acting adrenergic bronchodilator human drugs for oral inhalation*. Oral pressurized metered-dose inhalers containing the following active moieties:

- (i)–(ii) [Reserved]
- (iii) Metaproterenol.
- (iv) Pirbuterol.
- (v) Epinephrine.
- (3) [Reserved]

(4) *Other essential uses*. (i)–(ii) [Reserved]

(iii) Anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application.

(iv) Metered-dose cromolyn sodium human drugs administered by oral inhalation.

(v) [Reserved]

(vi) Metered-dose atropine sulfate aerosol human drugs administered by oral inhalation.

(vii) Metered-dose nedocromil sodium human drugs administered by oral inhalation.

(viii) Metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use.

(ix) Sterile aerosol talc administered intrapleurally by thoracoscopy for human use.

(f) Any person may file a petition under part 10 of this chapter to request that FDA initiate rulemaking to amend paragraph (e) of this section to add an essential use. FDA may initiate notice-and-comment rulemaking to add an essential use on its own initiative or in response to a petition, if granted.

(1) If the petition is to add use of a noninvestigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the product without ODSs;

(ii) The product will provide an unavailable important public health benefit; and

(iii) Use of the product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the unavailable important public health benefit.

(2) If the petition is to add use of an investigational product, the petitioner must submit compelling evidence that:

(i) Substantial technical barriers exist to formulating the investigational product without ODSs;

(ii) A high probability exists that the investigational product will provide an unavailable important public health benefit; and

(iii) Use of the investigational product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the high probability of an unavailable important public health benefit.

(g) Any person may file a petition under part 10 of this chapter to request that FDA initiate rulemaking to amend paragraph (e) of this section to remove an essential use. FDA may initiate notice-and-comment rulemaking to remove an essential use on its own initiative or in response to a petition, if granted. If the petition is to remove an essential use from paragraph (e) of this section, the petitioner must submit compelling evidence of any one of the following criteria:

(1) The product using an ODS is no longer being marketed; or

(2) After January 1, 2005, FDA determines that the product using an ODS no longer meets the criteria in paragraph (f) of this section after consultation with a relevant advisory committee(s) and after an open public meeting; or

(3) For individual active moieties marketed as ODS products and represented by one new drug application (NDA):

(i) At least one non-ODS product with the same active moiety is marketed with the same route of administration, for the same indication, and with approximately the same level of convenience of use as the ODS product containing that active moiety;

(ii) Supplies and production capacity for the non-ODS product(s) exist or will exist at levels sufficient to meet patient need;

(iii) Adequate U.S. postmarketing use data is available for the non-ODS product(s); and

(iv) Patients who medically required the ODS product are adequately served by the non-ODS product(s) containing that active moiety and other available products; or

(4) For individual active moieties marketed as ODS products and represented by two or more NDAs:

(i) At least two non-ODS products that contain the same active moiety are being marketed with the same route of delivery, for the same indica-

tion, and with approximately the same level of convenience of use as the ODS products; and

(ii) The requirements of paragraphs (g)(3)(ii), (g)(3)(iii), and (g)(3)(iv) of this section are met.

[67 FR 48384, July 24, 2002, as amended at 71 FR 70873, Dec. 7, 2006; 70 FR 17192, Apr. 4, 2005]

EFFECTIVE DATE NOTE: At 73 FR 69552, Nov. 19, 2008, §2.125 was amended by removing and reserving paragraph (e)(2)(v), effective December 31, 2011.

PART 3—PRODUCT JURISDICTION

Subpart A—Assignment of Agency Component for Review of Premarket Applications

Sec.

- 3.1 Purpose.
- 3.2 Definitions.
- 3.3 Scope.
- 3.4 Designated agency component.
- 3.5 Procedures for identifying the designated agency component.
- 3.6 Product jurisdiction officer.
- 3.7 Request for designation.
- 3.8 Letter of designation.
- 3.9 Effect of letter of designation.
- 3.10 Stay of review time.

Subpart B [Reserved]

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 360bbb–2, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

SOURCE: 56 FR 58756, Nov. 21, 1991, unless otherwise noted.

Subpart A—Assignment of Agency Component for Review of Premarket Applications

§ 3.1 Purpose.

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101–629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA