

§2.110

21 CFR Ch. I (4–1–14 Edition)

Thus these secondhand bags are potential sources of contamination of the food or animal feed stored or shipped therein.

(c) In a policy statement issued April 11, 1968, the Food and Drug Administration declared adulterated within the meaning of section 402(a) of the Federal Food, Drug, and Cosmetic Act shipments of vegetables or other edible food in used crates or containers that may render the contents injurious to health. This policy statement is extended so that the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of vegetables, other edible food, or animal feed in used crates, bags, or other containers that may render the contents injurious to health.

Subparts C–E [Reserved]

Subpart F—Caustic Poisons

§2.110 Definition of ammonia under Federal Caustic Poison Act.

For the purpose of determining whether an article containing ammonia is subject to the Federal Caustic Poison Act, the ammonia content is to be calculated as NH_3 .

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 con-

tained 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)–(v) [Reserved]

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

(i)–(v) [Reserved]

(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)–(v) [Reserved]

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

(vii)–(viii) [Reserved]

(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