secondhand containers have been rendered dangerous to health. Such contamination has been the result of the original use of these containers for the storage and shipment of articles containing or bearing disease organisms or poisonous or deleterious substances.

(b) The Commissioner concludes that such dangerous or potentially dangerous practices include, but are not limited to, the following:

1. Some vegetable growers and packers employ used poultry crates for shipment of fresh vegetables, including cabbage and celery. Salmonella organisms are commonly present on dressed poultry and in excreta and fluid exudates from dressed birds. Thus wooden crates in which dressed poultry have been iced and packed are potential sources of Salmonella or other enteropathogenic microorganisms that may contaminate fresh vegetables which are frequently consumed without heat treatment.

2. Some potato growers and producers of animal feeds use secondhand bags for shipment of these articles. Such bags may have originally been used for shipping or storing pesticide-treated seed or other articles bearing or containing poisonous substances. 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]
(iv) Pirbuterol.
(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) [Reserved]
  (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 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 indication, 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.


EFFECTIVE DATE NOTE: At 75 FR 19241, Apr. 14, 2010, §2.125 was amended by removing and reserving paragraphs (e)(2)(iv) and (e)(4)(viii), effective Dec. 31, 2013.

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]


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

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

§ 3.2 Definitions.

For the purpose of this part:


(b) Agency component means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, or alternative organizational component of the agency.

(c) Applicant means any person who submits or plans to submit an application to the Food and Drug Administration for premarket review. For purposes of this section, the terms “sponsor” and “applicant” have the same meaning.

(d) Biological product has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(e) Combination product includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;