

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the FDA Regional Food and Drug Director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of the FDA for processing under the EPIA or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order he shall order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or appropriate State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(f) *Inspection.* Persons engaged in retail distribution of shell eggs shall permit authorized representatives of FDA to make at any reasonable time such inspection of the retail establishment in which shell eggs are being held, including inspection and sampling of

such eggs and the equipment in which shell eggs are held and any records relating to such equipment or eggs, as may be necessary in the judgement of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(g) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement allowing refrigeration of unpasteurized shell eggs at retail establishments at any temperature greater than 7.2 °C (45 °F).

[65 FR 76112, Dec. 5, 2000]

PART 119—DIETARY SUPPLEMENTS THAT PRESENT A SIGNIFICANT OR UNREASONABLE RISK

AUTHORITY: 21 U.S.C. 321, 342, 343, 371.

§ 119.1 Dietary supplements containing ephedrine alkaloids.

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

[69 FR 6853, Feb. 11, 2004]

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

- Sec.
- 120.1 Applicability.
 - 120.3 Definitions.
 - 120.5 Current good manufacturing practice.
 - 120.6 Sanitation standard operating procedures.
 - 120.7 Hazard analysis.
 - 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.
 - 120.9 Legal basis.
 - 120.10 Corrective actions.
 - 120.11 Verification and validation.
 - 120.12 Records.