directions including, when indicated, the settings of equipment that have been determined to yield an adequately mixed Type A medicated article(s) of the specified formula.

(5) Control instructions, procedures, specifications, special notations, and precautions to be followed.

(b) A separate batch-production and control record shall be prepared for each batch or run of Type A medicated article(s) produced and shall be retained for at least 2 years after distribution by the manufacturer has been completed. The batch-production and control record shall include:

(1) Product identification, date of production, and endorsement by a competent and responsible individual.

(2) Records of each step in the manufacturing, packaging, labeling, and controlling of the batch, including dates, specific identification of drug components used, weights or measures of all components, laboratory-control results, mixing times, and the endorsements of the individual actively performing or the individual actively supervising or checking each step in the operation.

(3) A batch number that permits determination of all laboratory-control procedures and results on the batch and all lot or control numbers appearing on the labels of the Type A medicated article(s).

§ 226.110 Distribution records.

Complete records shall be maintained for each shipment of Type A medicated article(s) in a manner that will facilitate the recall, diversion, or destruction of the Type A medicated article(s), if necessary. Such records shall be retained for at least 2 years after the date of the shipment by the manufacturer and shall include the name and address of the consignee, the date and quantity shipped, and the manufacturing dates, control numbers, or marks identifying the Type A medicated article(s) shipped.

§ 226.115 Complaint files.

Records shall be maintained for a period of 2 years of all written or verbal complaints concerning the safety or efficacy of each Type A medicated article(s). Complaints shall be evaluated by competent and responsible personnel and, where indicated, appropriate action shall be taken. The record shall indicate the evaluation and the action.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

Subpart A—Drugs Regarded as Misbranded

Sec.
250.11 Thyroid-containing drug preparations intended for treatment of obesity in humans.
250.12 Stramonium preparations labeled with directions for use in self-medication regarded as misbranded.

Subpart B—New Drug or Prescription Status of Specific Drugs

250.100 Amyl nitrite inhalant as a prescription drug for human use.
250.101 Amphetamine and methamphetamine inhalers regarded as prescription drugs.
250.102 Drug preparations intended for human use containing certain ''coronary vasodilators''.
250.103–250.104 [Reserved]
250.105 Gelsemium-containing preparations regarded as prescription drugs.
250.106–250.107 [Reserved]
250.108 Potassium permanganate preparations as prescription drugs.

Subpart C—Requirements for Drugs and Foods

250.201 Preparations for the treatment of pernicious anemia.

Subpart D—Requirements for Drugs and Cosmetics

250.250 Hexachlorophene, as a component of drug and cosmetic products.

AUTHORITY: 21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b).

SOURCE: 40 FR 14033, Mar. 27, 1975, unless otherwise noted.

Subpart A—Drugs Regarded as Misbranded

§ 250.11 Thyroid-containing drug preparations intended for treatment of obesity in humans.

(a) Investigation by the Food and Drug Administration has revealed that a large number of drug preparations