

PROPOSED RULES

14215

(b) Technical services. . . .

(1) The builder-developer proposing a new subdivision which will have 10 or more dwelling sites will secure the services of a site planner, architect, landscape architect, or engineer, registered or otherwise certified as qualified in the state in which the subdivision is to be constructed, to provide complete planning, drawings, specifications, and supervision on land, street, utility and grading development.

(2) Complete technical services will be obtained and paid for by the builder-developer with his own funds.

(3) At completion of construction (or when construction will be accomplished in phases, at the end of each phase), the person who is qualified and registered or certified in the state in which the subdivision is to be constructed and is providing supervisory services during the period of work shall notify the FEA County Office in writing that all work has been completed in substantial conformance with the approved plans and specifications.

2. Amend § 1804.67 as follows:

§ 1804.67 Streets.

(a) New subdivisions and expansion of existing subdivisions.

(1) Streets must conform to master street plans, design standards and construction specifications of the applicable public body, city, town, county or state and the requirements of the FEA. Developments with more than 20 sites shall have two accesses available, unless an exception is granted by the State Director.

(48 U.S.C. 1490's; delegation of authority by Sec. of Agr., 38 FR 14944, 14948, 7 CFR 2.33; Delegation of authority by the Asst. Sec. for Rural Development, 38 FR 14944, 14962, 7 CFR 2.70).

Dated: April 15, 1974.

FRANK B. ELLIOTT,
Administrator,
Farmers Home Administration.

[FD Doc. 74-6152 Filed 4-19-74; 8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
[21 CFR Parts 310 and 700]

VINYL CHLORIDE AS AN INGREDIENT OF DRUG AND COSMETIC AEROSOL PRODUCTS

Notice of Proposed Rule Making

In the FEDERAL REGISTER of May 17, 1973 (38 FR 12931), the Commissioner of Food and Drugs published a notice of proposed rulemaking for prior-sanctioned polyvinyl chloride (PVC) resin. Polyvinyl chloride is a polymeric resin produced by polymerization of vinyl chloride which was used as a component of food packaging materials prior to the passage of the Food Additive Amendments of 1958 and which has been widely

used since that time. Only certain formulations of PVC, however, are prior-sanctioned for use in food packaging and therefore are exempt from classification as food additives and may be used without pre-marketing clearance by the Food and Drug Administration.

Early in 1973, the Food and Drug Administration began receiving reports of possible migration problems of ingredients of PVC bottles then being test marketed for distilled spirits. As a result of further analytical testing, the Commissioner published the May 17, 1973 proposal wherein he concluded that the use of PVC for the packaging of alcoholic foods may cause such foods to be adulterated. No PVC bottles have been used for such purposes since then. After the publication of the proposal, the Commissioner began investigating scientific reports regarding the possible migration of PVC container ingredients to nonalcoholic foods as well. Agency action on this matter and on the earlier proposal is expected to be published shortly in the FEDERAL REGISTER. The Commissioner is also considering the applicability of this information to various drug products packaged in PVC, and to various devices composed in whole or in part of PVC which may come in contact with drug fluids, or which may be inserted or implanted in the human body.

Because of the broad interest in the subject of vinyl chloride by both the public and the scientific community because of its potential as a serious threat to the public health, the Commissioner has undertaken an agency-wide effort to explore the problem in connection with those products within the jurisdiction of the Food and Drug Administration and to fashion the appropriate regulatory actions that should be taken to assure full protection of the public health. Representatives of this agency are also members of a Federal inter-agency task force formed to gather data on the overall effect of vinyl chloride on the total environment and to initiate coordinated action to minimize this impact.

In connection with this search for information, the Commissioner is particularly interested in receiving data in response to the following points relating to the use of polyvinyl chloride in containers for food and cosmetics, and in devices:

(1) The extent of usage of polyvinyl chloride by type of container or container liner and type of product.

(2) The vinyl chloride content in polyvinyl chloride used to manufacture or line various food and cosmetic containers, including description of the methods and extraction systems used to determine this content.

(3) The rate and level of vinyl chloride extraction from the aforementioned containers or their liners by various foods and cosmetics, including data derived after periods of storage.

(4) The rate and level of percutaneous absorption of vinyl chloride from cosmetics and devices when in contact with skin, in or mucous membrane.

(5) The vinyl chloride content of vari-

ous drug fluids after they have been in contact with devices composed in whole or in part of polyvinyl chloride.

(6) The effect on blood and tissues of vinyl chloride extracted from devices composed in whole or in part of polyvinyl chloride inserted or implanted in the body.

All persons in possession of such data are urgently requested to submit it to the Food and Drug Administration in writing (preferably in quintuplicate), if at all possible on or before June 21, 1974. This data should be sent to the Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, MD 20852. Received data may be seen in the above office during working hours, Monday through Friday.

The Commissioner recently received a petition from the Health Research Group, 2000 P Street NW., Washington, D.C. 20036, proposing to prohibit immediately the continued use of vinyl chloride as a constituent or propellant of cosmetic aerosol products and of polyvinyl chloride as a container material for any cosmetic product which can leach out detectable amounts of vinyl chloride from the polyvinyl chloride container material. The petitioner contends that there is substantial evidence that vinyl chloride monomer is carcinogenic.

A copy of the petition and letter of transmittal to the Commissioner are on file in the Office of the Hearing Clerk.

The Commissioner has reviewed all cosmetic product ingredient statements on file with the agency, representing approximately 50 percent of current market formulations, as of February 1, 1974, and has ascertained that no information exists in these files indicating use of vinyl chloride in cosmetic aerosol products. Furthermore, the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), has informed the Food and Drug Administration that the results of a recent telephone poll, covering 26 companies including the major aerosol hair spray manufacturers, show that no company contacted has manufactured products containing vinyl chloride since June 1973. In 1973, according to this information, two companies produced vinyl chloride-containing products with a total volume of approximately 1,625,000 units. The CTFA estimates that the percentage of hair spray cans manufactured in 1973 which contained vinyl chloride is less than 0.4 percent. A copy of the information received from the CTFA is on file in the Office of the Hearing Clerk.

There is no known past or present usage of vinyl chloride as a propellant in food aerosol products. Any such use without a food additive regulation would be a violation of the Federal Food, Drug, and Cosmetic Act.

With regard to drug products, the Food and Drug Administration has recently reviewed its files and conducted a survey of all known drug manufacturers of aerosol products to determine the extent to which vinyl chloride is used as a component, including propellant, in such products. The only known use of vinyl chloride in drug products is that of a

propellant in aerosol preparations. While all the information requested in the petition was submitted by manufacturers, the review of the agency files and preliminary results of the survey indicate that vinyl chloride is not currently being used in aerosol drug products. There are no approved new drug applications for vinyl chloride as a component of any drug. There is evidence, however, that manufacturers of some over-the-counter drug products used vinyl chloride as a propellant until 1973.

To determine the full extent that vinyl chloride is used in drug products and to determine if any additional action is needed to protect the public, there is published elsewhere in this issue of the *Federal Register*, a notice, pursuant to § 132.7(a)(4) (21 CFR 132.7(a)(4)), of the regulations under the Drug Listing Act of 1972, requiring all registrants to submit a list of all drug products marketed containing the ingredient vinyl chloride or packaged in containers composed of or lined with polyvinyl chloride.

The Commissioner has determined that there are sufficient scientific data on which to base a decision that: (1) vinyl chloride presents an unnecessary hazard to the public health when it is used as an ingredient in cosmetic aerosol products and that such use should be banned, and (2) vinyl chloride, when used as an ingredient in drug aerosol products, is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, and requires an approved new drug application as a condition of marketing.

There is ample evidence that vinyl chloride inhalation can result in acute toxicity manifested by an array of symptoms, including unconsciousness as a result of high concentration of inhalation. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported in animals. Reported studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Of most significance, however, is the fact that vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride to PVC. The scientific articles providing this evidence are on file in the Office of the Hearing Clerk. In view of this evidence, the Commissioner concludes that the banning of vinyl chloride as an ingredient in drug and cosmetic aerosol products is required. These products are often used in the confines of a small room where the level of vinyl chloride to which the individual may be exposed, although usually only for a short time, could be significantly in excess of the safe level established in connection with occupational exposure.

As a corollary to this conclusion, the Commissioner has requested all known manufacturers of such products with supplies still on the market to recall these supplies from the market to the retail level, and similar requests will be

made of any additional such manufacturers if and as they are located.

Two cosmetic aerosol hair spray manufacturers commenced such recalls as of April 2, 1974 and a drug and cosmetic manufacturer, identified after a file search, began recall of seven drug and three cosmetic aerosol products as of April 8, 1974, following an April 4, 1974 request.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 501(a), 701(a); 52 Stat. 1050-1055, as amended; 21 U.S.C. 352, 355, 361(a), 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that Parts 310 and 700 be amended as follows:

1. By adding a new § 310.506 to Subpart E of Part 310 to read as follows:

§ 310.506 Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products.

(a) Vinyl chloride has been used as a propellant in aerosol drug preparations. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness when inhaled at high concentrations. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have been reported in animals. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Recently, vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride.

(b) The Commissioner finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of aerosol drug preparations containing vinyl chloride as an ingredient, including propellant. Therefore, any such product containing vinyl chloride is a new drug and a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD-1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that such preparations are safe and effective for the purposes intended.

(d) Any such drug within the jurisdiction of the act which is not in accord with this regulation is subject to regulatory action.

2. By adding a new § 700.14 to Subpart B of Part 700 to read as follows:

§ 700.14 Use of vinyl chloride as an ingredient, including propellant of cosmetic aerosol products.

(a) Vinyl chloride has been used as an ingredient in cosmetic aerosol products including hair sprays. Where such aerosol products are used in the confines of a small room, as is often the case, the level of vinyl chloride to which the indi-

vidual may be exposed could be significantly in excess of the safe level established in connection with occupational exposure. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness when inhaled at high concentrations. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Furthermore, vinyl chloride has recently been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride. It is the view of the Commissioner that vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated under section 501(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Any cosmetic aerosol product containing vinyl chloride as an ingredient shipped within the jurisdiction of the act is subject to regulatory action.

Interested persons may, on or before May 22, 1974, file with the Hearing Clerk, Food and Drug Administration, room 6-36, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: April 16, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.
[FR Doc. 74-5223 Filed 4-19-74; 8:45 am]

DEPARTMENT OF TRANSPORTATION

COAST GUARD

[33 CFR Part 117]

[OGD 74115]

NEW RIVER SOUND AND STRANAHAN RIVER, FLA.

Proposed Drawbridge Operation Regulations

At the request of the Florida Yacht Club Council, the Coast Guard is considering revoking the regulations for the East Las Olas Boulevard drawbridge across the Atlantic Intracoastal Waterway in Fort Lauderdale, Florida, to require that the draw open on signal. Present regulations allow closed periods from November 15 through May 15 from 7 a.m. to 6 p.m. during which the draw need only open on the hour and half hour. This change is being considered for the following reasons:

(a) The regulations presently in force were issued on March 15, 1950 (15 FR 1461), and were amended on July 2, 1953 (18 FR 3782), October 22, 1955 (20 FR 8118), and October 20, 1956 (21 FR 8064). These regulations were issued to ease ve-