the denial order issued against the respondent on February 28, 1972 (37 FR 4306).

Dated: April 12, 1976.

RAUER H. MEYER,
Director,
Office of Export Administration.

[FR Doc.74-9080 Filed 4-19-74;8:45 am]

COMPUTER SYSTEMS TECHNICAL ADVISORY COMMITTEE

Notice of Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given that a meeting of the Licensing Procedures Subgroup of the Computer Systems Technical Advisory Committee will be held Monday, April 29, 1974, at 1:30 p.m. in Conference Room A, Main Commerce Building, 14th and Constitution Avenue, Washington, D.C.

Members advise the Office of Export Administration, Bureau of East-West Trade, with respect to questions involving technical matters, worldwide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to computer systems, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls.

Agenda items are as follows:

1. Opening remarks by the Chairman, Computer Systems Technical Advisory Committee.
2. Appointment of subgroup chairman.
3. Presentation of papers or comments by the public.
4. Discussion of export licensing procedures relating to computer systems.
5. Executive Session: Continuation of discussion of export licensing procedures.

The public will be permitted to attend the discussion of agenda items 1-4, and a limited number of seats will be available to the public for these agenda items. To the extent time permits, members of the public may present oral statements to the subgroup. Interested persons are also invited to file written statements with the subgroup.

With respect to agenda item 5, "Executive Session," the Assistant Secretary of Commerce for Administration, on December 20, 1973, determined, pursuant to section 10(d) of Public Law 92-463, that this agenda item should be exempt from the provisions of sections 10 (a)(1) and (a)(3), relating to open meetings and public participation therein, because the meeting will be concerned with matters listed in 5 U.S.C. 552(b)(1).

Further information may be obtained from John L. Collins, Chairman, Computer Systems Technical Advisory Committee, IBM World Trade Corporation, 1801 K Street NW., Washington, D.C. 20006 (A/C 202-833-6000).

Minutes of those portions of the meeting which are open to the public will be available 30 days from the date of the meeting upon written request addressed to: Central Reference and Records Inspection Facility, U.S. Department of Commerce, Washington, D.C. 20230.

Dated: April 17, 1974.

RAUER H. MEYER,
Director, Office of Export Administration, Bureau of East-West Trade, Department of Commerce.

[FR Doc.74-9089 Filed 4-19-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[NADA No. 48-236V]

AGRITRONICS CORP.

Agritronics Swine Premix T-S; Withdrawal of Approval of New Animal Drug Application

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351; 21 U.S.C. 360b) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), the following notice is issued:

Agritronics Corp., 811 24th St., Des Moines, IA 50311, has requested that its NADA (new animal drug application) No. 48-236V be withdrawn is accordance with § 135.28(d) (21 CFR 135.28(d)) on the grounds that the drug is not being marketed. Notice is given that approval of NADA No. 48-236V for Agritronics Swine Premix T-S, which contains tylosin and sulfamethazine, is hereby withdrawn.

Effective date. This notice shall be effective April 22, 1974.

Dated: April 15, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-9114 Filed 4-19-74;8:45 am]

HUMAN DRUGS CONTAINING VINYL CHLORIDE OR PACKAGED IN POLYVINYL CHLORIDE CONTAINERS

Notice to Drug Manufacturers, Packers, and Distributors

Elsewhere in this issue of the FEDERAL REGISTER (39 FR 14215) the Commissioner of Food and Drugs has proposed that all aerosol drug products containing vinyl chloride as a component, including propellant, are new drugs and subject to regulatory proceedings unless the products are the subject of new drug applications approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act. That proposal is based on scientific data demonstrating that vinyl chloride is not generally recognized as safe and effective as a component, including propellant, of a drug product.

The Food and Drug Administration is aware that vinyl chloride has been used as a propellant in aerosol drug preparations, but has no information that vinyl chloride is currently being used in the manufacture of drug products. 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 inhalation. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported in animals. In addition, there are studies demonstrating the carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride, and it has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of the monomer to polyvinyl chloride.

Polyvinyl chloride, a polymeric resin produced by polymerization of vinyl chloride, is used in drug packaging materials. There is evidence of vinyl chloride migration when polyvinyl chloride is used in packaging material for products containing alcohol. There have also been reports of the possible migration of polyvinyl chloride container ingredients to non-alcoholic products as well. Because of this it is necessary to give special study to such packaging material to determine if it is safe for its intended use.

For these reasons it is essential that the Commissioner have knowledge of every drug product currently marketed in the United States that contains vinyl chloride as an ingredient, and information regarding every marketed drug product packaged in a polyvinyl chloride container or in a container lined with polyvinyl chloride. Such information is necessary for determining if there is adequate evidence whether drugs containing vinyl chloride or packaged in containers composed of, or lined with, polyvinyl chloride are safe and effective for their intended purposes and what action, if any, is required to protect the public health.

Section 510(j)(3) of the act, as added by the Drug Listing Act of 1972, authorizes the Commissioner to require each registrant under section 510 of the act to submit a list of each drug product which the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution and which contains a particular ingredient, when the Commissioner has made a finding that the submission of such a list is necessary to carry out the purposes of the act. For the reasons stated above the Commissioner so finds with regard to drugs containing vinyl chloride. As packaging materials are an integral part of the drug product, the Commissioner also so finds with regard to drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners.

In addition to the required list of drugs containing vinyl chloride and a required list of drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners, the Commissioner is requesting, but not requiring, that certain other information be submitted. The Commissioner acknowledges that some of the information being requested has also been requested in the regulations implementing the Drug Listing Act of 1972, and will be available

from that source. However, it will greatly simplify the compilation of this information if it is included in this submission.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 510, 701(a), 52 Stat. 1040–1042, as amended, 1053, as amended, 1055, as amended; 21 U.S.C. 321, 360, 371(a); 42 U.S.C. 262) and under authority delegated to the Commissioner (21 CFR 2.120), each registrant under section 510 of the act is required to submit to the Food and Drug Administration a list of all human drugs which are being manufactured, prepared, propagated, compounded, or processed for commercial distribution and which contain vinyl chloride whether or not the vinyl chloride is an active or inactive ingredient and a list of all human drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners as follows:

1. Reporting firm name, address, and registration number.
2. List of drugs containing vinyl chloride (by trade name, if any, and established name, if any) and a list of drug products for which polyvinyl chloride is used as a container or a container liner (by trade name, if any, and established name, if any).

It is requested but not required that the following information also be submitted:

3. National Drug Code (NDC) if one has been assigned.
4. A statement whether the drug is marketed over the counter or limited to prescription distribution.
5. Route of administration.
6. Amount of vinyl chloride in average daily dose.
7. Quantity of drug distributed (number of dosage units) during previous 12 months.
8. A copy of the label and labeling.

In addition to the information requested in items 1 through 8 (excluding item 6) for drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners it is requested, but not required, that the following information be submitted.

9. A statement of the vinyl chloride content in polyvinyl chloride used for the manufacture of the drug container or container lining. Include description of the methods and extraction systems used to determine this content. If this information is not known, provide the name and address of the drug container or container liner supplier and/or manufacturer.

10. The rate and level of extraction of vinyl chloride from the polyvinyl chloride containers or container liners by the particular drug or by any other extraction or solvent systems, including data derived after periods of storage. Where such information is not known, but is or may be available from the supplier or manufacturer of the container or liner, provide the name and address of such supplier or manufacturer.

11. The rate and level of absorption of vinyl chloride as an ingredient or of vinyl chloride extracted from a polyvinyl chloride container or liner by the drug contained on an average daily dose. Where such information is not known, but is or may be available from the supplier or manufacturer of the container or liner, provide the name and address of such supplier or manufacturer.

12. Name and address of the manufacturer of the polyvinyl chloride resin, where such information is known.

This information shall be submitted to:

Department of Health, Education, and Welfare
Food and Drug Administration
Bureau of Drugs, Drug Listing Staff (BFD–7)
5600 Fishers Lane
Rockville, MD 20852

by May 22, 1974.

Dated: April 15, 1974.

A. M. Schmidt,
Commissioner of Food and Drugs.

[FR Doc.74-9231 Filed 4-19-74;8:45 am]

ADVISORY COMMITTEES

Notice of Meetings

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463, 86 Stat. 770–776; 5 U.S.C. App.), the Food and Drug Administration announces the following public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a) (1) and (2) of the act:

Committee name	Date, time, place	Type of meeting and contact person
1. Panel on Review of Internal Analgesic including Antirheumatic Drugs.	May 6 and 9, 9 a.m., Conference Room C, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open May 6, 9 a.m. to 10 a.m., closed May 6, after 10 a.m., closed May 9. Lee Geismar, Room 10B–05, 5600 Fishers Lane, Rockville, Md. 20852, 301–443–4960.

Purpose. Reviews and evaluates available information concerning safety and effectiveness of active ingredients of currently marketed non-prescription drug products containing internal analgesic agents.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continuing review of nonprescription internal analgesic drugs under investigation.

Committee name	Date, time, place	Type of meeting and contact person
2. Panel on Review of Orthopaedic Devices	May 11, 9 a.m., Hotel Utah Motor Lodge, Salt Lake City, Utah.	Open 9 a.m. to 10 a.m., closed after 10 a.m. James R. Veale (HFM–120), 5600 Fishers Lane, Rockville, Md. 20852, 301–443–3320.

Purpose. Reviews and evaluates available data concerning safety, effectiveness, and reliability of orthopaedic devices currently in use.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continuation of review of previous classification results and identification of specific areas for standards for those devices classified as requiring standards.

Committee name	Date, time, place	Type of meeting and contact person
3. Panel on Review of Dental Devices.	May 21 and 22, 9 a.m., American Dental Association Bldg., Chicago, Ill.	Open May 22, 9 a.m. to 10 a.m., closed May 22 after 10 a.m., closed May 23. Robert S. Kennedy, Ph.D., (HFM–130) 5600 Fishers Lane, Rockville, Md. 20852, 301–443–2378.

Purpose. Reviews and evaluates available data concerning the safety, effectiveness, and reliability of dental devices currently in use.

Agenda. Open session: Comments and presentations by interested persons; device classification; and device legislation. Closed session: Continuing review and classification of dental devices.

Agenda items are subject to change as priorities dictate.

During the open sessions shown above, interested persons may present relevant information or views orally to any committee for its consideration. Information or views submitted to any committee in writing before or during a meeting shall also be considered by the committee.

A list of committee members and summary minutes of meetings may be obtained from the contact person for the committee both for meetings open to the public and those meetings closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act.

Most Food and Drug Administration advisory committees are created to advise the Commissioner of Food and Drugs on pending regulatory matters. Recommendations made by the committees on these matters are intended to result in action under the Federal Food, Drug, and Cosmetic Act, and these committees thus necessarily participate with the Commissioner in exercising his law enforcement responsibilities.

The Freedom of Information Act recognized that the premature disclosure of regulatory plans, or indeed internal discussions of alternative regulatory approaches to a specific problem, could have adverse effects upon both public and private interests. Congress recognized that such plans, even when finalized, may not be made fully available in advance of the effective date without damage to such interests, and therefore provided for this type of discussion to remain confidential. Thus, law enforcement activities have long been recognized as a legitimate subject for confidential consideration.

These committees often must consider trade secrets and other confidential information submitted by particular manufacturers which the Food and Drug Administration by law may not disclose, and which Congress has included within the exemptions from the Freedom of Information Act. Such information includes safety and effectiveness information, product formulation, and manufacturing methods and procedures, all

(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 FHA 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 FHA. Developments with more than 20 sites shall have two accesses available, unless an exception is granted by the State Director.

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(42 U.S.C. 1480's; delegation of authority by Sec. of Agri., 38 FR 14944, 14948, 7 CFR 2.23; 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.74-9152 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 the skin or mucous membrane.

(5) The vinyl chloride content of various 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 has been as a

propellant in aerosol preparations. While all the information requested in the survey was not supplied 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, 601(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 where 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 individual 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 where 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 601(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 6–86, 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.74-9232 Filed 4-19-74;8:45 am]

DEPARTMENT OF TRANSPORTATION

COAST GUARD

[33 CFR Part 117]

[CGD 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 28, 1955 (20 FR 8118), and October 20, 1956 (21 FR 8094). These regulations were issued to ease re-