PVC 52.0.

the denial order issued against the respondent on February 28, 1972 (37 FR 5306).

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.74-9099 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 (HFD–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 8 and 9, 9 a.m., Conference Room C, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open May 8, 9 a.m. to 10 a.m., closed May 8, 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, 301–443–3550.

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 22 and 23, 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–120) 5600 Fishers Lane, Rockville, Md. 20852, 301–443–2376.

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