annual reports and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 7–112	Nisaval (pyrilamine maleate) 25 milligram (mg) Tablets.	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
NDA 11–863	Flavihist Cough Syrup	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 50–042	Potassium Penicillin G Diagnostic Sensitivity Powder, 20,000 units.	Pfizer Inc., 235 East 42d St., New York, NY 10017–5755.
NDA 50–067	Compocillin-VK Chewable Wafers	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 50–088	Unipen Injection	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 50–121	Compocillin-VK Tablets	Abbott Laboratories.
NDA 50–122	Compocillin-V Chewable Wafers	Do.
NDA 50–129	Pen-Vee Suspension and Drops	Wyeth-Ayerst Laboratories.
NDA 50–189	Omnipen Tablets	Do.
NDA 50–197	Unipen Injection	Do.
NDA 50–305	Unipen Capsules	Do.
NDA 50–319	Omnipen Chewable Tablets	Do.
NDA 50–413	Geopen Diagnostic Susceptibility Powder	Pfizer Inc.
ANDA 87–387	Aminophylline Injection USP,25 mg/milliliter	Pharma-Serve, Inc., 218–20 98th Ave., Queens Village, NY 11429.

Therefore, notice is given to the holders of the applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before January 4, 1999, a written notice of participation and request for a hearing, and (2) on or before February 1, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: November 12, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–32069 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and

recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 18, 1998, 10:15 a.m. to 5:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Michael G. Bazaral, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 140, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12624. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on general issues related to the classification of tracheal gas insufflation (TGI) devices used to provide part or all of the breathing gas for treatment of respiratory failure or respiratory insufficiency. The use of the TGI catheter, tube or lumen only for supply of fresh gas distinguishes TGI from common tracheal tubes and tracheostomy tubes, in which the gas flow alternates between inhalation and exhalation. The draft versions of five questions FDA will ask the committee to address are listed as follows:

1. For the evaluation of effectiveness of specific TGI systems as an adjunct to ventilation of adults, is reduction of minute ventilation (or PCO_2) without appreciable increase in end-expiratory lung volume or pressure a sufficient endpoint? Is this the correct endpoint?

2. For ventilation of adults, is there now sufficient understanding of TGI to be reasonably sure that TGI, with adequate monitoring and other understood safety provisions, will not have worse outcomes? Or does TGI raise concerns that will require that FDA review data on patient outcomes?

3. Are there special considerations about the data FDA should review for TGI submissions in relation to ventilation of children, infants, newborns, or premature infants?

4. What are the minimum system functions that include all the functions needed to provide TGI for clinical use as an adjunct to or replacement for conventional ventilation?

5. What specific safety provisions are important? Is distal pressure monitoring essential?

Procedure: On December 18, 1998, from 12:15 p.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present information or views, orally or in writing, on issues pending before the committee. Written submissions must be made to the contact person by December 11, 1998. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m., and between approximately 4 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 11, 1998, and submit a brief statement of the general nature of the arguments they wish to present, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 18, 1998, from 10:15 a.m. to 12:15 p.m., the meeting will be closed to permit FDA to present trade secret and/or confidential commercial information (5 U.S.C. 522b(c)(4)) regarding pending issues and applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 24, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–32024 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–259]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Evaluation of the EverCare Demonstration; *Form No.:* HCFA–R–259; Use: This survey will capture information on the quality of capitated Medicare coverage to nursing home residents, such as the description of the person, information regarding enrollment/disenrollment, quality of life, satisfaction including issues of access to services, advance medical directives, general health, and functional status. This information will be used to support analyses of enrollment decisions, access to services and providers, and outcomes for both the enrollee and family members. The underlying premise of the EverCare demonstration is that closer attention to primary care needs of high-risk patients through the use of nurse practitioners and/or physicians assistants can reduce the use of hospitals (and emergency rooms). *Frequency:* On occassion; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,150; *Total Annual Responses:* 3,150; *Total Annual Hours:* 1,962.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 16, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–32124 Filed 12–1–98; 8:45 am]

BILLING CODE 4120–03–P