

B. Conditions for approval and marketing. The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Oxycodone hydrochloride, oxycodone terephthalate, aspirin, caffeine and phenacetin combination preparations are in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The labels bear the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The "Indications" are as follows:

INDICATIONS

For relief of moderate to moderately severe pain.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and an abbreviated supplement or updating information, as described in paragraphs (a)(1)(i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new drug application, the submission of an abbreviated new drug application as described in paragraph (a)(3)(i) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 7337, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852:

Supplements (identify with NDA number):
Office of Scientific Evaluation (BD-100),
Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-60),
Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-66),
Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat.

1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: December 6, 1972.

SAM D. FINE,
Associate Commissioner for
Compliance.

[FR Doc. 72-21308 Filed 12-8-72; 8:48 am]

[DESI 13334; Docket No. FDC-D-569;
NDA 13-334]

MERCK SHARP AND DOHME

Dexamethasone Sodium Phosphate and Lidocaine Hydrochloride Injection, Dilute; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

In an announcement (DESI 13334) published in the FEDERAL REGISTER of September 23, 1970 (35 F.R. 14800), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following drug:

That part of NDA 13-334 pertaining to Decadron Phosphate with Xylocaine Injection, Dilute containing dexamethasone sodium phosphate 1 mg./ml. and lidocaine hydrochloride 5 mg./ml.; Merck Sharp and Dohme, Division of Merck and Co. Inc., West Point, Pa. 19486.

The announcement stated there is a lack of substantial evidence that this fixed combination drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug application for this drug.

Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcement. No data providing substantial evidence of effectiveness have been received.

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of pertinent parts of the listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug(s) will have all the effects purported or represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new

drug application(s) reviewed. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of pertinent parts of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) for the labeling claims involved, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the

conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. The hearing contemplated by this notice will be open to the public except that any portion of the

hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in this appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: November 30, 1972.

SAM D. FINE,
Associate Commissioner for
Compliance.

[FR Doc.72-21309 Filed 12-8-72;8:48 am]

DEPARTMENT OF TRANSPORTATION

Hazardous Materials Regulations Board

SPECIAL PERMITS

Notice of Issuance

Pursuant to Docket No. HM-1, rule making procedures of the Hazardous Materials Regulations Board, issued May 22, 1968 (33 F.R. 8277) 49 CFR 170, following is a list of new DOT Special Permits upon which Board action was completed during November 1972:

Special permit No.	Issued to—Subject	Mode or modes of transportation
6682	Foot Mineral Company, Exton, Pa., to ship lithium metal foil on spools in hermetically sealed steel cans inside Specification 21C fiber drums.	Highway, rail.
6683	Shippers registered with this Board to ship caustic soda, liquid in DOT Specification 17E steel drums which have been reconditioned as prescribed in §173.28(m).	Highway, rail.
6684	Shippers registered with this Board to ship whiskey in non-DOT specification stainless steel portable tanks.	Highway, cargo vessel.
6685	U.S. Department of Defense, Washington, D.C., to ship a Class A explosive (cyclo-tetramethylene tetranitramine (HMX), wet) in DOT Specification 21C fiber drums in temperature controlled motor vehicles.	Highway.
6686	Shippers registered with this Board to ship methyl acetylene-propadiene, stabilized, in DOT Specification 39 cylinders having brazed seams.	Highway, rail.
6687	PPG Industries, Inc., Pittsburgh Pa., to ship an aerosol formulation in 20-ounce (fluid) non-refillable metal inside containers.	Passenger-carrying Aircraft.
6688	Shippers registered with this Board to ship compressed air in non-DOT specification seamless cylinders made of aluminum alloy designated 8351-T8.	Highway, rail.
6689	Shippers registered with this Board to ship a gas generator, and a argon-helium mixture in an inflator assembly patterned after DOT Specification 39.	Highway.
6693	Trojan-U.S. Powder, Allentown, Pa., to ship surplus trinitrotoluene (TNT) in non-DOT specification metal boxes.	Highway.

Following is a list of requests for special permits which were denied during November 1972:

DENIED—SUBJECT

1. Request by Exotic Metal Fabricators Co., Seattle, Wash. for a special permit to ship compressed air in non-DOT specification welded, high pressure, stainless steel cylinders.

G. ROUSSEAU,
Alternate Secretary.

[FR Doc.72-21233 Filed 12-8-72;8:45 am]

ATOMIC ENERGY COMMISSION

[License No. 05-13943-01E]

STATITROL CORP.

Notice of Issuance of Amendment of Byproduct Material License

Please take notice that the Atomic Energy Commission has, pursuant to

§ 32.26 of 10 CFR Part 32, issued Amendment No. 5 to License No. 05-13943-01E to Statitrol Corp., 140 South Union Boulevard, Lakewood, CO 80228, which authorizes the distribution of Model 720 ionization fire detector to persons exempt from the requirements for a license pursuant to § 30.20 of 10 CFR Part 30.

1. The devices are designed to detect incipient fires by responding to the prod-

ucts of combustion produced by thermal decomposition of building materials or contents prior to the appearance of visible smoke, flame, or appreciable heat. The sensitive element of the detector is an ionization chamber in which air flowing into the chamber is made conductive by alpha particles emitted by americium 241.

2. The byproduct material incorporated in the detector is americium in the oxide form contained in foils manufactured by Nuclear Radiation Developments (Model A-001) or by the Radiochemical Centre (Model AMM). The nominal activity contained in the unit is 1.0 microcurie but the maximum activity is 1.3 microcuries.

3. Each exempt unit will have a label identifying the manufacturer (Statitrol Corp.) and the byproduct material (americium 241) contained in the unit and recommending that the unit be returned to the Statitrol Corp. for repair or disposal.

A copy of the amended license and a safety evaluation containing additional information, prepared by the Directorate of Licensing, are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, DC.

For the Atomic Energy Commission.

Dated at Bethesda, Md., this 2d day of December 1972.

S. H. SMILEY,
Deputy Director, for Fuels and
Materials, Directorate of Li-
censing.

[FR Doc.72-21234 Filed 12-8-72;8:45 am]

CIVIL AERONAUTICS BOARD

CHASE MANHATTAN BANK

Notice of Meeting

Notice is hereby given that a meeting with the above bank will be held on January 12, 1973, at 10 a.m. (local time) in Room 1027, Universal Building, 1825 Connecticut Avenue NW., Washington, D.C., to make a presentation on the future availability of petroleum as it relates to aviation fuel.

Dated at Washington, D.C., December 5, 1972.

[SEAL]

HARRY J. ZINK,
Secretary.

[FR Doc. 72-21249 Filed 12-8-72;8:45 am]

[Docket No. 24897]

MILLARDAIR, LTD.

Postponement of Prehearing Conference and Hearing

Notice has been received from Millardair, Ltd., that it is unable to submit proposed amendment to its application.