

NEW DRUGS

Reports of Information for Drug Effectiveness

The National Academy of Sciences-National Research Council (NAS-NRC) has agreed to assist the Food and Drug Administration in its review of the claims of effectiveness for drugs cleared through the new-drug procedures from 1938 until October 10, 1962. To facilitate this review and a determination of whether there may be ground for invoking section 505(e) of the Federal Food, Drug, and Cosmetic Act, and to provide each holder of such an approved new-drug application an opportunity to present for the consideration of the reviewing experts the best data available to support the medical claims, this order is entered pursuant to section 505 of the act:

1. Each holder of a new-drug application approved between 1938 and October 10, 1962, shall report the following, in duplicate, preferably on forms which have been devised by the National Academy of Sciences-National Research Council and which are available for the purpose from the Food and Drug Administration or any of its offices:

a. New-drug application number, date originally approved, and whether R_x or OTC drug.

b. Brand name of drug or preparation.

c. Applicant's (firm's) name and address.

d. Quantitative formula using established (nonproprietary) name of active ingredients.

e. Dosage form and route of administration. Where a new-drug application covers different routes of administration, separate forms should be used.

f. Current labels and package inserts (attach 10 copies of each to original of form; 1 copy of each to duplicate).

g. List of literature references most pertinent to an evaluation of the effectiveness of the drug for the purposes for which it is offered in the label, package insert, or brochure. Approximately 5 to 10 key references, if available (attach 10 copies of the list to original of form and 1 copy to duplicate).

h. Unpublished articles or other data pertinent to an evaluation of the claims (one copy only; attach to duplicate).

2. This report shall be made as promptly as possible and no later than 60 days from the date of this publication in the FEDERAL REGISTER, shall be plainly marked on the outside of the envelope or package "Special Drug Report," and shall be addressed to the Director, Bureau of Medicine (or Director, Bureau of Veterinary Medicine, in the case of veterinary drugs), Food and Drug Administration, Washington, D.C. 20204.

3. The submission of this special report may be made without prejudice to any person's contention that he is not required by law to make the report.

4. This order is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(j), 52 Stat. 1052, amended, 76 Stat. 782, 21 U.S.C. 358(j)) and under the authority dele-

gated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.120; 31 F.R. 3008).

Dated: July 6, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 66-7489; Filed, July 8, 1966;
8:47 a.m.]

COMMISSIONS TO STATE AND LOCAL OFFICIALS

Revocation

For many years, pursuant to section 702(a) of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has commissioned State and local officials as officers of the Department of Health, Education, and Welfare to conduct examinations and investigations for the purposes of the act. Amendments to the act and concurrent administrative commitments now require a new commissioning policy; therefore:

1. All such commissions to State and local officials, including officials of the District of Columbia and the Commonwealth of Puerto Rico, are hereby revoked, and

2. Notice is given that revised commissioning procedures are being considered.

This action is taken pursuant to section 702(a) of the act (52 Stat. 1056, as amended; 21 U.S.C. 372(a)) and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.120; 31 F.R. 3008).

Dated: July 6, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 66-7490; Filed, July 8, 1966;
8:47 a.m.]

ATOMIC ENERGY COMMISSION

[Docket No. 50-256]

LOCKHEED-GEORGIA CO.

Notice of Issuance of Facility Export License

Please take notice that no request for a formal hearing having been filed following the publication of notice of proposed action in the FEDERAL REGISTER on June 18, 1966 (31 F.R. 8548), the Atomic Energy Commission has issued License No. XR-61 to Lockheed-Georgia Co., a division of Lockheed Aircraft Corp., authorizing export of a 10-kilowatt pool-type heterogeneous research reactor to the Comision Nacional de Energia Atomica, Montevideo, Uruguay. The export of this reactor to Uruguay is within the purview of the present Agreement for Cooperation between the Government of the United States of America and the International Atomic Energy Agency.

Dated at Bethesda, Md., this 5th day of July 1966.

For the U.S. Atomic Energy Commission.

EBER R. PRICE,
Director, Division of
State and Licensee Relations.

[F.R. Doc. 66-7470; Filed, July 8, 1966;
8:45 a.m.]

CIVIL AERONAUTICS BOARD

[Docket No. 17423]

AEROVIAS CONDOR DE COLOMBIA, LTDA.

Postponement of Prehearing Conference

Application for amendment of its foreign air carrier permit so as to add the intermediate point Curacao, N.W.I. on its route between Miami and points in Colombia with respect to property only.

At the request of Counsel for Applicant the prehearing conference now scheduled to be held in the above-entitled proceeding on July 12, 1966, is hereby postponed to be held on July 19, 1966, at 10 a.m., e.d.s.t., in Room 911, Universal Building, Connecticut and Florida Avenues N.W., Washington, D.C., before the undersigned examiner.

Dated at Washington, D.C., July 5, 1966.

[SEAL]

WALTER W. BRYAN,
Hearing Examiner.

[F.R. Doc. 66-7491; Filed, July 8, 1966;
8:47 a.m.]

[Docket No. 16236; Order No. E-23894]

INTERNATIONAL AIR TRANSPORT ASSN.

Order Relating to Specific Commodity Rates

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 1st day of July 1966.

Agreement adopted by the Joint Conferences of the International Air Transport Association relating to specific commodity rates Docket 16236, Agreement C.A.B. 18934.

An agreement has been filed with the Board, pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, between various air carriers, foreign air carriers, and other carriers, embodied in the resolutions of the joint conferences of the International Air Transport Association (IATA), and adopted at the third meeting of the Joint Specific Commodity Rates Committee held in London, May 3 through May 13, 1966. The agreement has been assigned the above-designated C.A.B. Agreement number.

Basically, the agreement, as it applies to air transportation as defined by the Act, extends for a further period of effectiveness specific commodity rates established since the Venice Cargo Conference held in May 1965. The agreement also, as set forth in the attach-