

TX-226, Mesquite Livestock Commission Co., Mesquite, Tex., Jan. 21, 1959.

TX-235, Havard's Horse Sale, Nacogdoches, Tex., Feb. 7, 1967.

TX-239, Palestine Commission Company, Palestine, Tex., June 5, 1967.

TX-260, Sonora Livestock Exchange Company, Sonora, Tex., Sept. 15, 1965.

Notice or other public procedure has not preceded promulgation of the foregoing rule. There is no legal justification for not promptly deposing a stockyard which is no longer within the definition of that term contained in the Act.

The foregoing is in the nature of a rule relieving a restriction and may be made effective in less than 30 days after publication in the FEDERAL REGISTER. This notice shall become effective upon publication in the FEDERAL REGISTER (2-19-72).

(42 Stat. 159, as amended and supplemented; 7 U.S.C. 181 et seq.)

Done at Washington, D.C., this 10th day of February 1972.

EDWARD L. THOMPSON,
Acting Chief, Registrations,
Bonds, and Reports Branch,
Livestock Marketing Division.

[FR Doc.72-2529 Filed 2-18-72;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 2354]

COMBINATION DRUG CONTAINING PHENOBARBITAL, ACETAMINOPHEN, PHENACETIN, ATROPINE SULFATE, SCOPOLAMINE HYDROBROMIDE, AND HYOSCYAMINE HYDROBROMIDE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug:

Hasamal tablets containing phenobarbital, acetaminophen, phenacetin, atropine sulfate, scopolamine hydrobromide, and hyoscyamine hydrobromide; Charles C. Haskell Division, Arnar-Stone Laboratories, Inc., 601 East Kensington Road, Mount Prospect, Ill. 60056 (NDA 2-354).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that the drug:

1. Is possibly effective for relief of pain in headache or toothache, and for symptomatic relief of primary dysmenorrhea.
2. Lacks substantial evidence of effectiveness as a fixed combination for relief of fever.

3. Lacks substantial evidence of effectiveness for relief of cough associated with upper respiratory infection.

B. *Marketing status.* 1. Within 60 days of the date of publication of this announcement in the FEDERAL REGISTER, the holder of any previously approved new-drug application for which the drug is classified in paragraph A above as lacking substantial evidence of effectiveness is requested to submit a supplement to his application, as needed, to provide for revised labeling which deletes those indications for which substantial evidence of effectiveness is lacking. Such a supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new-drug regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time, and the revised labeling should be put into use within the 60-day period. Failure to do so may result in a proposal to withdraw approval of the new-drug application.

2. If any such preparation is on the market without an approved new-drug application, its labeling should be revised if it includes those claims for which substantial evidence of effectiveness is lacking as described in paragraph A above. Failure to delete such indications and put the revised labeling into use within 60 days after the date of publication hereof in the FEDERAL REGISTER may cause the drug to be subject to regulatory proceedings.

3. The notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273), (f) the marketing status of a drug labeled with those indications for which it is regarded as possibly effective.

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 2354, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

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

Original new-drug applications: Office of
Scientific Evaluation (BD-100), Bureau of
Drugs.

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

All other communications regarding this
announcement: Drug Efficacy Study Imple-
mentation 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: January 27, 1972.

R. E. DUGGAN,
Acting Associate Commissioner
for Compliance.

[FR Doc.72-2550 Filed 2-18-72;8:45 am]

[DESI 7110; Docket No. FDC-D-291; NDA 7-110, etc.]

CORTISONE; DEXAMETHASONE; HYDROCORTISONE; METHYLPREDNISOLONE; PREDNISOLONE; AND TRIAMCINOLONE FOR PARENTERAL USE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following glucocorticoid drugs:

1. Aristocort Forte Suspension, containing triamcinolone diacetate; Lederle Laboratories, Division American Cyanamid Co., Pearl River, N.Y. 10965 (NDA 12-802).

2. Aristocort Intralesional Suspension, containing triamcinolone diacetate; Lederle Laboratories (NDA 11-685).

3. Cortef Acetate Sterile Injectable Suspension, containing hydrocortisone acetate; The Upjohn Co., 7171 Portage Road, Kalamazoo, Michigan 49002 (NDA 9-378).

4. Cortef Sterile Aqueous Suspension, containing hydrocortisone; The Upjohn Co. (NDA 9-864).

5. Cortef Sterile Solution, containing hydrocortisone; The Upjohn Co. (NDA 9-379).

6. Cortiphate Injection, containing hydrocortisone sodium phosphate; Travenol Laboratories, Inc., Division of Baxter Laboratories, Inc., 6301 Lincoln Avenue, Morton Grove, Illinois 60053 (NDA 12-784).

7. Cortisone Acetate Aqueous Suspension; Vitamix Pharmaceuticals, Inc., 2900 North 17th Street, Philadelphia, Pennsylvania 19132 (NDA 10-603).

8. Cortisone Acetate Sterile Aqueous Suspension; The Upjohn Co. (NDA 8-126).

9. Cortone Acetate Saline Suspension, containing cortisone acetate; Merck, Sharp & Dohme, Division of Merck & Co., Inc., West Point, Pa. 19486 (NDA 7-110).

10. Cortril Aqueous Suspension, containing hydrocortisone acetate; marketed by Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, New York 10017 (NDA 9-164).

11. Cortril Soluble Parenteral, containing hydrocortisone sodium succinate; Chas. Pfizer & Co. (NDA 10-291).

12. Decadron Phosphate Injection, containing dexamethasone sodium phosphate; Merck, Sharp & Dohme (NDA 12-071).

13. Deltacortril Aqueous Suspension, containing prednisolone acetate; Chas. Pfizer & Co. (NDA 11-158).

14. Depo-Medrol Aqueous Suspension, containing methylprednisolone acetate; The Upjohn Co. (NDA 11-757).

15. Hy-Cor Acetate Aqueous Suspension, containing hydrocortisone acetate; Gold Leaf Pharmacal Co., subsidiary of Ormont Drug & Chemical Co., Inc., 223 South Dean Street, Englewood, N.J. 07631 (NDA 9-786).