

15128 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

[From the Federal Register, vol. 39, No. 140, July 19, 1974, pp. 26459-62]

NOTICES

[DESI 5378; Docket No. FDC-D-687; NDA 5-378, etc.]

DRUGS FOR HUMAN USE—DRUG EFFICACY STUDY IMPLEMENTATION CERTAIN SINGLE ENTITY ORAL ANORECTIC DRUGS IN CONVENTIONAL OR CONTROLLED RELEASE DOSAGE FORMS

FOLLOW-UP NOTICE AND OPPORTUNITY FOR HEARING

The Food and Drug Administration published an announcement in the Federal Register of August 8, 1970 (35 FR 12678) regarding the efficacy of the following single entity oral anorectic drugs:

1. Biphetamine "7½" Capsules, Biphetamine "12½" Capsules, and Biphetamine "20" Capsules, respectively, containing 3.75 milligrams, 6.25 milligrams, and 10 milligrams each of dextroamphetamine and amphetamine per capsule, all as cation exchange resin complexes of sulfonated polystyrene; Strassenburgh Laboratories, Division of Wallace and Tiernan Inc., Post Office Box 1710, Rochester, NY 14603 (NDA 10-093).

2. Ionamin "15" Capsules and Ionamin "20" Capsules, containing, respectively, 15 milligrams phentermine and 30 milligrams phentermine per capsule, both as cation exchange resin complexes of sulfonated polystyrene; Strassenburgh Laboratories Division of Wallace and Tiernan Inc. (NDA 11-613).

3. Methedrine Tablets containing 5 milligrams methamphetamine hydrochloride per tablet; formerly marketed by Burroughs Wellcome & Co., Inc., 3030 Cornwallis Road, Research Triangle Park, NC 27709 (NDA 5-504).

4. Amphetroxyn Hydrochloride Tablets containing 5 milligrams methamphetamine hydrochloride per tablet; Eli Lilly and Co., Post Office Box 618, Indianapolis, Ind. 46206 (NDA 6-390).

5. Delfetamine Stedytabs containing 30 milligrams di-methamphetamine hydrochloride per controlled release tablet; Eastern Research Laboratories, Inc., 302 South Central Ave., Baltimore, MD 21202 (NDA 12-416).

6. Desoxyn Tablets containing 2.5 milligrams or 5 milligrams methamphetamine hydrochloride per tablet, Desoxyn Gradumet Tablets containing 5, 10, or 15 milligrams methamphetamine hydrochloride per tablet, and Desoxyn Elixir containing 20 milligrams methamphetamine hydrochloride per 30 milliliters; Abbott Laboratories, 14th and Sheridan Road, North Chicago, Ill. 60064 (NDA 5-378).

7. Drinalfa Tablets containing 5 milligrams methamphetamine hydrochloride per tablet; E. R. Squibb, P.O. Box 400, Princeton, NJ 08544 (NDA 5-756).

8. Tenuate Dospan Tablets containing 75 milligrams diethylpropion hydrochloride per controlled release tablet; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 1100 East Amity Road, Cincinnati, OH 45215 (NDA 12-546).

9. Racemic Desoxyephedrine Hydrochloride Tablets containing 5 milligrams di-methamphetamine hydrochloride per tablet; High Chemical Co., 1760 North Howard Street, Philadelphia, PA 19122 (NDA 5-969).

10. Miller-Drine Tablets containing 10 milligrams di-methamphetamine hydrochloride per tablet; Smith, Miller and Patch, Inc., 401 Joyce Kilmer Avenue, New Brunswick, NJ 08902 (NDA 6-003).

11. Norodin Tablets containing 5 milligrams methamphetamine hydrochloride per tablet; Endo Laboratories, 1000 Stewart Avenue, Garden City, Long Island, NY 11533 (NDA 6-632).

12. D-O-E Tablets containing 5 milligrams methamphetamine hydrochloride per tablet, Tilden-Yates Laboratories, Inc., 295 Lafayette Street, New York, NY 10012 (NDA 5-603).

Of the new drug applications listed above, approval of the following applications and supplements thereto, was withdrawn August 8, 1972 (37 FR 15948) on the grounds that the applicants had not made required reports under section 505(j) of the Act (21 U.S.C. 355(j)) and §§ 310.300 or 310.302 (e) and (f) of the new-drug regulations (21 CFR 310.300, 310.302):

NDA 5-632, Norodin Tablets (methamphetamine hydrochloride); Endo Laboratories.

NDA 6-390, Amphetroxyn Hydrochloride Tablets (methamphetamine hydrochloride); Eli Lilly and Company.