

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

[Docket No. 01P-0252]

Determination That Dextroamphetamine Sulfate Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that dextroamphetamine sulfate 15-milligram (mg) tablets (formerly marketed by Lannett Co., Inc.) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dextroamphetamine sulfate 15-mg tablets.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98-417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug which was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA’s regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Dextroamphetamine sulfate tablets, 15 mg, are the subject of approved ANDA 85–652 held by Lannett Co., Inc. Dextroamphetamine sulfate tablets are indicated for narcolepsy and for attention deficit disorder with hyperactivity. Lannett Co., Inc.’s, dextroamphetamine sulfate 15-mg tablets are currently listed in the “Discontinued Drug Product List” section of the Orange Book.

On May 17, 2001, Mallinckrodt, Inc., submitted a citizen petition (Docket No. 01P–0252/CP1) to FDA under 21 CFR 10.20 and 10.30. The petition, as amended July 26, 2001, requested that the agency determine that dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from the market for reasons of safety or effectiveness.

The agency has determined that dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. There are several grounds for FDA's finding. First, there are drug products containing 15-mg dextroamphetamine sulfate being marketed today. Although these drug products are extended release products rather than immediate release products, FDA has concluded that this difference does not affect the product's safety. Second, the petitioner identified no data or other information suggesting that dextroamphetamine sulfate tablets, 15 mg, were withdrawn from sale as a result of safety or effectiveness concerns. Third, Lannett Company, Inc., informed FDA in June 1993 that its entire product line had been recalled following a change in management, and the agency has found no information that would lead it to conclude otherwise. Finally, FDA has also independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined above, Lannett Co.'s dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list dextroamphetamine sulfate tablets, 15 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List"

identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to dextroamphetamine sulfate tablets, 15 mg, may be approved by the agency.

Dated: 10/10/02
October 10, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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Dawn P. Hawkins