

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002P-0431]

Determination That Delcobese (Amphetamine Adipate, Amphetamine Sulfate, Dextroamphetamine Adipate, Dextroamphetamine Sulfate) Tablets and Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets and capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for generic versions of Delcobese tablets and capsules.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), 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 that 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 (the 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 “Approved Drug Products with Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under 314.161(a)(1) of the act (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.

Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets (1.25 milligrams (mg), 2.5 mg, 3.75 mg, 5 mg) were the subject of approved ANDA 83–563. Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) capsules (1.25 mg, 2.5 mg, 3.75 mg, 5 mg) were the subject of approved ANDA 83–564. Both ANDAs were submitted by Delco Chemical Co., but ownership was later transferred to Lemmon Co. Delcobese tablets and capsules were labeled for the

following indications: (1) Narcolepsy; (2) behavioral syndrome characterized by hyperactivity, distractability, and impulsiveness in children (currently commonly known as attention deficit hyperactivity disorder or ADHD); and (3) exogenous obesity. Prior to Delcobese's discontinuation, FDA proposed to remove the exogenous obesity indication from the labeling of all drug products containing an amphetamine, including Delcobese products, and offered the application holders an opportunity for hearing (44 FR 41552, July 17, 1979). That notice is still pending. While it is pending, the exogenous obesity indication may not be approved for ANDAs relying on Delcobese tablets or capsules as their listed drug (21 CFR 314.127(a)(9)).

On February 22, 1985, Lemmon Co. notified FDA that Delcobese capsules had not been manufactured since March 1984. On June 4, 1990, FDA requested that Lemmon Co. withdraw ANDAs 83-563 and 83-564 because the marketing of both Delcobese capsules and tablets had been discontinued. On February 24, 1993, Lemmon Co. requested the withdrawal of ANDAs 83-563 and 83-564. Accordingly, FDA withdrew approval of the applications in a **Federal Register** notice (58 FR 27737, May 11, 1993). Delcobese was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book.

In a citizen petition submitted under 21 CFR 10.30 dated September 20, 2002 (Docket No. 02P-0431), as amended by a letter dated October 23, 2002, Sonnenschein Nath & Rosenthal requested that FDA determine whether Delcobese tablets and capsules were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Delcobese tablets and capsules were not withdrawn from sale for reasons of safety or effectiveness. The petitioners

identified no data or other information suggesting that Delcobese tablets and capsules were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant data, including postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness. Finally, an NDA for a similar amphetamine/dextroamphetamine salt combination was recently approved after the product was found to be safe and effective for the treatment of ADHD.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined above, Delcobese tablets and capsules, approved under ANDAs 83-563 and 83-564, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Delcobese tablets and capsules in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing

for reasons other than safety or effectiveness. As a result, ANDAs that refer to Delcobese tablets and capsules may be approved by the agency for appropriate indications.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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