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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2007-P-0326]

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Certifier A. Corbin

**Determination That SANOREX (Mazindol) Tablets 1 and 2 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

AGENCY: Food and Drug Administration, HHS.

73FR40582  
7/15/08

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing its determination that SANOREX (mazindol) Tablets, 1 and 2 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for mazindol tablets if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Carol E. Drew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306 Silver Spring, MD 20993-0002, 301-796-3601.

**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 applicants 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. ANDA applicants 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.

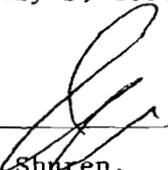
The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed 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). Regulations also provide that the agency must make a determination as to 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 (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On August 20, 2007, AAIPharma submitted a citizen petition (Docket No. 2007P-0326/CP1) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether SANOREX (mazindol) Tablets, 1 and 2 mg (NDA 17-247), manufactured by Novartis Pharmaceuticals Corp. (Novartis), were withdrawn from sale for reasons of safety or effectiveness. SANOREX is approved for the management of exogenous obesity as a short term adjunct in a regimen of weight reduction based on caloric restriction in certain patients. SANOREX Tablets were approved on June 14, 1973. SANOREX Tablets were discontinued in 1999, and the drug product was moved from the

prescription drug product list to the “Discontinued Drug Product List” section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that SANOREX Tablets, 1 and 2 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that SANOREX Tablets, 1 and 2 mg, were withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list SANOREX Tablets 1 and 2 mg 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. ANDAs that refer to SANOREX (mazindol) Tablets, 1 and 2 mg, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: 7/3/08  
July 3, 2008.

  
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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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