

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No FDA-2008-P-0125] (formerly Docket No. 2007P-0172)

**Determination That MINOCIN (Minocycline Hydrochloride) Capsules
Equivalent to 75 Milligrams Base Was Not Withdrawn From Sale for Reasons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) is announcing its determination that MINOCIN (minocycline hydrochloride) Capsules equivalent to (EQ) 75 milligrams (mg) base was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for minocycline hydrochloride capsules 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

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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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

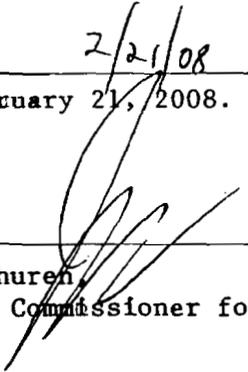
On May 1, 2007, Kendle International, on behalf of Aurobindo Pharmaceuticals, Ltd., submitted a citizen petition (Docket No. 2007P-0172/CP1) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether MINOCIN (minocycline hydrochloride) Capsules EQ 75 mg base (NDA 050-649), manufactured by Triax Pharmaceuticals, Ltd. (Triax), was withdrawn from sale for reasons of safety or effectiveness. MINOCIN is a tetracycline-class antibiotic medicine used to treat certain infections caused by bacteria. MINOCIN Capsules EQ 75 mg base was approved on February 12, 2001. Our records show that the 75 mg strength of this product was marketed

for a short period of time in 2001. MINOCIN Capsules EQ 75 mg base were discontinued in September 2001 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 MINOCIN Capsules EQ 75 mg base was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that MINOCIN Capsules EQ 75 mg base was 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 MINOCIN (minocycline hydrochloride) Capsules EQ 75 mg base 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 minocycline hydrochloride capsules EQ 75 mg base 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.

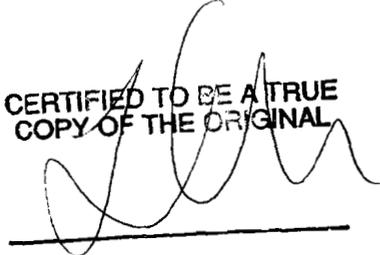
Dated: 2/21/08
February 21, 2008.



Jeffrey Shuren
Assistant Commissioner for Policy.

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