

DHB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket 2004P-0220]

Display Date	5-19-05
Publication Date	5-20-05
Certifier	J. Cooke

**Determination That ZITHROMAX (Azithromycin) 250-Milligram Oral 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Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**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and Drug Administration (FDA) has determined that ZITHROMAX (azithromycin) 250-milligram (mg) oral capsules were not withdrawn from sale for reasons of safety or effectiveness.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 azithromycin 250-mg oral capsules.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, 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 typically 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

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(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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

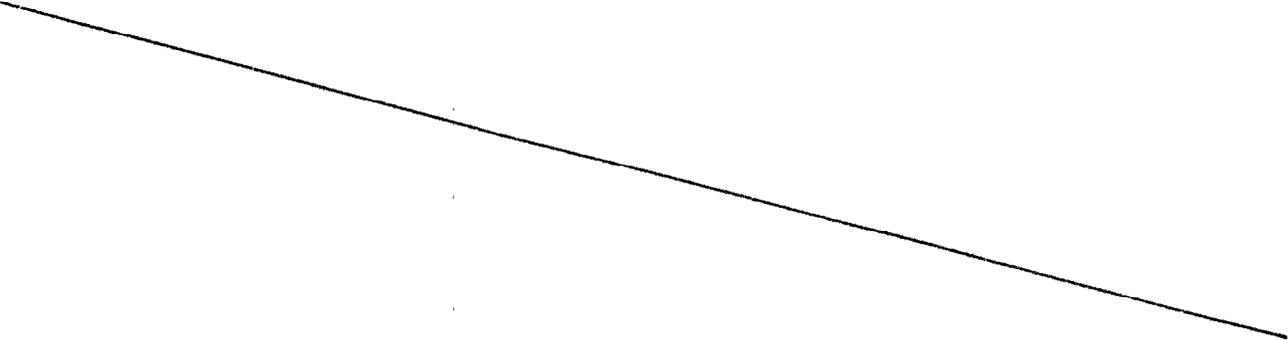
Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ZITHROMAX (azithromycin) 250-mg oral capsules are the subject of NDA 50-670 held by Pfizer, Inc. (Pfizer). FDA approved NDA 50-670 on November 1, 1991. In February 1994, Pfizer submitted NDA 50-711 for ZITHROMAX (azithromycin) 250-mg tablets. Pfizer explained that the new dosage form was intended to replace the capsule formulation. Pfizer decided to change the dosage form from capsules to tablets because tablets do not have a food effect. In its February 15, 1994, letter accompanying NDA 50-711, Pfizer explained that the tablets are bioequivalent to the capsule formulation and "* * * unlike the capsule, can be taken without regard to meals." After NDA 50-711 was approved, Pfizer decided not to market the capsule formulation and ZITHROMAX (azithromycin) 250-mg oral capsules were moved from the

prescription drug product list to 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.

In a citizen petition submitted under 21 CFR 10.30 dated May 4, 2004 (Docket No. 2004P-0220), as amended by a letter dated May 17, 2004, Wapner, Newman, Wigrizer & Brecher requested that FDA determine whether ZITHROMAX (azithromycin) 250-mg oral capsules were withdrawn from sale for reasons of safety or effectiveness. The agency has determined that ZITHROMAX (azithromycin) 250-mg oral capsules were not withdrawn from sale for reasons of safety or effectiveness. The petitioners identified no data or other information suggesting that ZITHROMAX (azithromycin) 250-mg oral capsules were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this document, ZITHROMAX (azithromycin) 250-mg oral capsules, approved under NDA 50-670, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZITHROMAX (azithromycin) 250-mg oral capsules

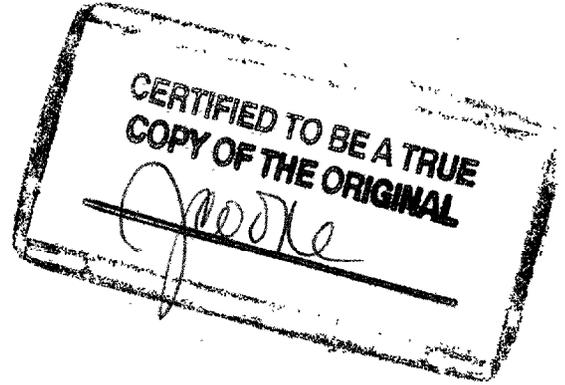


in the "Discontinued Drug Product List" section of the Orange Book. As a result, ANDAs that refer to ZITHROMAX (azithromycin) 250-mg oral capsules may be approved by the agency.

Dated: 5/12/05
May 12, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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