This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0028]

Determination That SEROQUEL (Quetiapine Fumarate) Tablets, 150 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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and Drug Administration (FDA) has determined that SEROQUEL (quetiapine fumarate) tablets, 150 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 quetiapine fumarate tablets, 150 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Quynh Nguyen, 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 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 generally known 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (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.

SEROQUEL (quetiapine fumarate) tablets, 150 mg, along with the 25–mg, 50–mg, 100–mg, 200–mg, 300–mg, and 400–mg strengths, are the subject of approved NDA 20–639 held by AstraZeneca Pharmaceuticals LP (AstraZeneca). SEROQUEL (quetiapine fumarate) tablets are in a class of medications called atypical antipsychotics. Antipsychotic medicines are used to treat symptoms of schizophrenia. SEROQUEL (quetiapine fumarate) tablets may be used alone or with lithium or divalproex to treat acute manic episodes in adults who have a condition called Bipolar I Disorder.

AstraZeneca obtained approval to market the 150–mg strength of SEROQUEL (quetiapine fumarate) tablets on December 20, 1998. Lachman Consultant Services, Inc., submitted a citizen petition dated January 16, 2007, (Docket No. 2007P–0028/CP1), under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether SEROQUEL (quetiapine fumarate) tablets, 150 mg, were withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition (including the comment(s) submitted) and reviewing agency records, the agency has determined that AstraZeneca's SEROQUEL (quetiapine fumarate) tablets, 150 mg, were not withdrawn from sale for reasons of safety or effectiveness. AstraZeneca has never marketed SEROQUEL (quetiapine fumarate) tablets, 150 mg, in the United States, although the 150–mg tablets are marketed in some countries outside the United States. In previous instances (see, e.g., 67 FR 79640, December 30, 2002 (addressing a relisting request for Diazepam Autoinjector)), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product in the United States is equivalent to withdrawing the drug from sale.

The petitioner identified no data or other information suggesting that SEROQUEL (quetiapine fumarate) tablets, 150 mg, were withdrawn from sale as a result of safety or effectiveness concerns. AstraZeneca has marketed other strengths of SEROQUEL (quetiapine fumarate) tablets: 25 mg, 50 mg, 100 mg, 200 mg, 300 mg, and 400 mg. The agency has reviewed its files for records concerning the withdrawal of SEROQUEL (quetiapine fumarate) tablets, 150 mg. There is no indication that AstraZeneca decided not to market SEROQUEL (quetiapine fumarate) tablets, 150 mg, in the United States for safety or effectiveness reasons. FDA has independently evaluated relevant literature and data for reports of adverse events and has found no information that would indicate that SEROQUEL (quetiapine fumarate) tablets, 150 mg, were withdrawn for reasons of safety or effectiveness.

FDA determines that for the reasons outlined in this document, AstraZeneca's SEROQUEL (quetiapine fumarate) tablets, 150 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list SEROQUEL (quetiapine fumarate) tablets, 150 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 SEROQUEL (quetiapine fumarate) tablets, 150 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for Seroquel (quetiapine fumarate) tablets, 150 mg, should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: January 16, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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