DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0295]

Determination That INDERAL (Propranolol Hydrochloride) Tablets, 10 Milligrams, 20 Milligrams, and 90 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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has determined that INDERAL (propranolol hydrochloride (HCl)) Tablets, 10 milligrams (mg), 20 mg, and 90 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to approve ANDAs for propranolol HCl tablets, 10 mg, 20 mg, and 90 mg as long as they meet relevant legal and regulatory requirements.

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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that referred to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug. FDA may not approve an ANDA that does not refer to a listed drug.

INDERAL (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg, and 90 mg, are the subject of approved NDA 16–418 held by Wyeth Pharmaceuticals, Inc. (Wyeth). INDERAL is indicated in the treatment of hypertension, angina pectoris, atrial fibrillation, myocardial infarction, migraine headaches, essential tremors, hypertrophic subaortic stenosis, and pheochromocytoma. In tablet form, INDERAL is currently available in 40-, 60-, and 80-mg strengths. Wyeth discontinued marketing the tablet form in the 10-, 20-, and 90-mg strengths, and those products were moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

In a citizen petition dated July 20, 2007 (Docket No. 2007P–0295/CP1), submitted under 21 CFR 10.25(a) and 10.30, Regulus Pharmaceutical Consulting, Inc., requested that the agency determine, as described in § 314.161, whether INDERAL (propranolol HCl) Tablets, 10 mg and 20 mg, were withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that INDERAL Tablets, 10 mg and 20 mg, were withdrawn from sale as a result of safety or effectiveness concerns. Although the citizen petition did not address the 90-mg strength, FDA must make a determination regarding whether that strength was withdrawn for safety or efficacy reasons because generic versions of that strength are currently being marketed.

We have reviewed our records and determined that INDERAL Tablets, 10 mg, 20 mg, and 90 mg, were not withdrawn from sale for reasons of safety or effectiveness. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that INDERAL Tablets, 10 mg, 20 mg, and 90 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA has determined that, for the reasons outlined in this notice, INDERAL (propranolol HCl) Tablets, 10 mg, 20 mg, and 90 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list INDERAL (propranolol HCl) Tablets, 10 mg, 20 mg, and 90 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 INDERAL (propranolol HCl) Tablets, 10 mg, 20 mg, and 90-mg, may be approved by the agency as long as they comply with relevant legal and regulatory requirements. 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: January 2, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA No. 225–07–8004]

Memorandum of Understanding Between the Food and Drug Administration and Regents of the University of California

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and