contained on pages 7 through 9 of the PHS 2590 (Rev. 5/95) form should be followed for reporting on research progress. Supplemental reporting instructions may be required depending on different FDA grant program requirements. After reviewing the noncompeting continuation application, the FDA program and/or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information in a timely manner may result in a delayed award.

FDA grants are funded under the legislative authority of section 301 of the Public Health Service Act (24 U.S.C. 241).

Dated: August 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20851 Filed 8–14–96; 8:45 am]

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[Docket Nos. 96P–0190/CP1, 96P–0197/CP1, 96P–0251/CP1]

Determination That Selegiline Hydrochloride 5-Milligram Tablet Was Not Withdrawn From Sale For Reasons of Safety or Effectiveness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and Drug Administration (FDA) has determined that selegiline hydrochloride (Eldepryl®) 5-milligram (mg) tablet was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for selegiline hydrochloride 5-mg tablet.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 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 under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), 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). 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.

Selegiline hydrochloride (Eldepryl®) 5-mg tablet is the subject of approved NDA 19–334, held by Somerset Pharmaceuticals, Inc. (Somerset). On May 17, 1996, Somerset withdrew the selegiline hydrochloride 5-mg tablet from sale, and began marketing in its place a capsule form of selegiline hydrochloride 5-mg (NDA 20–647).

On June 12, 1996, Novopharm Ltd. submitted under 21 CFR 10.30 a citizen petition (Docket No. 96P–0190/CP1) regarding the status of the selegiline hydrochloride 5-mg tablet. Two similar citizen petitions were subsequently received by the agency; a petition by Endo Laboratories, L.L.C. was filed on June 17, 1996 (Docket No. 96P–0197/CP1), and a petition submitted by Williams & Connolly on behalf of Alphapharm, Ltd. was filed on July 10, 1996 (Docket No. 96P–0251/CP1). The three petitions request that the agency determine whether the selegiline hydrochloride 5-mg tablet was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, keep the drug listed in the Orange Book.

The agency has reviewed its records and under § 314.161, has determined that the selegiline hydrochloride 5-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. In reaching its decision, FDA considered comments submitted by Somerset, in which Somerset asserted that the drug was withdrawn from sale for safety reasons. Somerset requested that FDA deny the citizen petitions.

Somerset claims that Eldepryl® 5-mg tablet was withdrawn from the market ''out of concern for the safety of patients with Parkinson's Disease.'' First, it refers to the appearance of counterfeit Eldepryl® tablets in the U.S. marketplace. This is not a problem unique to Eldepryl® and is not evidence that the product is unsafe.

Second, Somerset makes a nonspecific reference to ''the information contained in NDA # 19–334'' as confirmation that the removal of the tablet form of the drug was out of concern for the safety of patients. FDA's examination of this NDA found no evidence to support this claim. Somerset may have been alluding to reports of difficulty swallowing tablets in patients with Parkinson's Disease. That some patients may prefer an alternative dosage form is common with oral products regardless of the disease being treated. FDA does not regard providing a second dosage form that some patients may find more convenient than the first as evidence that the first is unsafe. Somerset may also have been alluding to reports of confusion between Eldepryl® tablets and enalapril. This is not a safety concern relevant to generic products because, among other reasons, they would not use the name Eldepryl® .

The agency concludes that Eldepryl® tablets were withdrawn from sale for reasons other than for safety or effectiveness. Accordingly, the agency will maintain selegiline hydrochloride 5-mg tablet 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. ANDA's that refer to selegiline hydrochloride 5-mg tablet may be approved by the agency.

Dated: August 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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