comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: June 15, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–15547 Filed 6–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0842]

Determination That Ranitidine Effervescent 75–Milligram Tablet Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) is announcing its determination that ranitidine effervescent 75-milligram (mg) tablet (Zantac Efferdose) was not withdrawn from sale for reasons of safety or effectiveness.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 ranitidine effervescent 75-mg tablet.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, 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 (the 1984 amendments) (Public Law 98–417), 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 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the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). 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.

Ranitidine effervescent 75-mg tablet is the subject of NDA 20–745. FDA approved NDA 20–745, held by Glaxo Wellcome, Inc. (Glaxo), on February 26, 1998. Glaxo never marketed the ranitidine effervescent 75-mg tablet. Glaxo transferred ownership of NDA 20–745 to the Warner-Lambert Co. (Warner-Lambert) effective January 1, 1999. To date, Warner-Lambert has not marketed the ranitidine effervescent 75-mg tablet.

On March 1, 2000, Thomas Blake, R.Ph., submitted a citizen petition (Docket No. 00P–0842/CP1) under 21 CFR 10.30 to FDA. The petition requested that the agency determine whether ranitidine effervescent 75-mg tablet was withdrawn from sale for reasons of safety or effectiveness. FDA has determined that, for the purposes of § 314.161, never marketing an approved drug product is equivalent to withdrawing the drug product from sale.

FDA has reviewed its records and, under § 314.161, has determined that the decision by Glaxo and Warner-Lambert not to market ranitidine effervescent 75-mg tablet was not for reasons of safety or effectiveness. Accordingly, the agency will maintain ranitidine effervescent 75-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 ranitidine effervescent 75-mg tablet may be approved by the agency.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–15555 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0585]

Determination That Fluoxetine Hydrochloride 20–Milligram Tablets 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) is announcing its determination that fluoxetine hydrochloride 20-milligram (mg) tablets (Prozac®) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for fluoxetine hydrochloride 20-mg tablets.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, 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 (the 1984 amendments) (Public Law 98–417), 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 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 (§ 314.162 (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 February 11, 2000, Lachman Consultant Services, Inc., submitted a citizen petition (Docket No. 00P–0585/CP1) under 21 CFR 10.30 to FDA. The petition requested that the agency determine whether fluoxetine hydrochloride 20-mg tablets were withdrawn from sale for reasons of safety or effectiveness. Fluoxetine hydrochloride 20-mg tablets are the subject of NDA 20–974. FDA approved NDA 20–974, held by Eli Lilly and Co., on March 9, 1999. On April 2, 1999, Eli Lilly and Co. informed FDA that it had decided not to market fluoxetine hydrochloride 20-mg tablets. FDA has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under § 314.161, has determined that Eli Lilly and Co.'s decision not to market fluoxetine hydrochloride 20-mg tablets was not for reasons of safety or effectiveness. Accordingly, the agency will continue to list fluoxetine hydrochloride 20-mg tablets 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 fluoxetine hydrochloride 20-mg tablets may be approved by the agency.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–15556 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0090]

Determination That Paroxetine Hydrochloride 10-, 20-, 30-, and 40-Milligram 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 paroxetine hydrochloride (Paxil) 10-, 20-, 30-, and 40-milligram (mg) capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for paroxetine hydrochloride 10-, 20-, 30-, and 40-mg capsules.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), 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,'' 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 (§ 314.162 (21 CFR 314.162)). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)) 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. FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated December 28, 1999 (Docket No. 00P–0090/CP1), submitted under 21 CFR 10.25(a), 10.30, and 314.122, Pentech Pharmaceuticals, Inc., requested that the agency determine whether paroxetine hydrochloride (Paxil) 10-, 20-, 30-, and 40-mg capsules were withdrawn or withheld from sale for reasons of safety or effectiveness. Paroxetine hydrochloride (Paxil) 10-, 20-, 30-, and 40-mg capsules are the subject of approved NDA 20–885 held by SmithKline Beecham Pharmaceuticals (SKB). SKB obtained approval to market the 10-, 20-, 30-, and 40-mg strengths of paroxetine hydrochloride capsules on October 9, 1998. SKB has never marketed the 10-, 20-, 30-, and 40-mg strengths of paroxetine hydrochloride capsules. FDA has determined, for purposes of §§ 314.161 and 314.162(c), that never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that paroxetine hydrochloride 10-, 20-, 30, and 40-mg capsules were not withdrawn from sale for reasons of safety or effectiveness. Accordingly the agency will maintain paroxetine hydrochloride 10-, 20-, 30-, and 40-mg capsules in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to paroxetine hydrochloride 10-, 20-, 30-, and 40-mg capsules may be approved by the agency.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–15630 Filed 6–20–00; 8:45 am]

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