Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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[Docket No. 95P–0285]

Determination That Glyburide Tablets 4.5 Milligrams Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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and Drug Administration (FDA) has determined that glyburide (Glynase® PresTab®) tablets 4.5 milligrams (mg) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow sponsors to submit abbreviated new drug applications (ANDA's) for glyburide tablets 4.5 mg.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law 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 (the 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Another FDA regulation also provides that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))).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.

Novopharm Ltd., submitted a citizen petition, dated August 21, 1995 (Docket No. 95P–0285/CP1), under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether glyburide tablets 4.5 mg 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, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Glyburide tablets 4.5 mg, along with the 1.5-mg, 3-mg, and 6-mg strengths, is the subject of approved NDA 20–051 held by the Upjohn Co. (Upjohn). Upjohn obtained approval to market the 4.5-mg strength of glyburide tablets on September 24, 1993. Upjohn has never marketed the 4.5-mg strength of glyburide tablets. 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 for sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that glyburide tablets 4.5 mg was not withdrawn from sale for reasons of safety or effectiveness and will continue to list glyburide tablets 4.5 mg in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to glyburide tablets 4.5 mg may be submitted to the agency.

The agency notes that there is a patent listed in the Orange Book for Glynase® PresTab® tablets that will not expire until April 10, 2007. This patent will prevent FDA from approving ANDA's that refer to Glynase® PresTab® tablets with an effective date before April 10, 2007, if the patent is valid and the manufacture, use, or sale of the drug product for which approval is being sought would infringe the patent. Novopharm Ltd., states in its petition that it does not intend to make a generic drug that refers to Glynase® PresTab® tablets available for sale until the expiration of the patent. Between now and the time an ANDA for glyburide tablets 4.5 mg is submitted, approved, or the approval goes into effect, FDA may obtain new information on the safety and effectiveness of glyburide tablets that will prevent the agency from receiving or approving the ANDA.

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12759 Filed 5–20–96; 8:45 am]

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[Docket No. 95P–0128]

Determination That Hydrocortisone Acetate Topical Ointment 2.5% 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 hydrocortisone (Cortef®) acetate topical ointment 2.5% was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow sponsors to submit abbreviated new drug applications (ANDA's) for hydrocortisone acetate topical ointment 2.5%.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law 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 (the 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 (§ 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 May 12, 1995, Reed & Carnrick Pharmaceuticals submitted a citizen petition (Docket No. 95P–0128/CP1) under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether hydrocortisone acetate topical ointment 2.5% 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, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Hydrocortisone acetate topical ointment 2.5%, along with the 1% strength, is the subject of approved NDA 8–917 held by the Upjohn Co. (Upjohn). On July 28, 1953, Upjohn obtained approval to market the 2.5% strength of hydrocortisone acetate topical ointment. Upjohn withdrew the drug from sale in 1991.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that hydrocortisone acetate topical ointment 2.5% was not withdrawn from sale for reasons of safety or effectiveness and will continue to list hydrocortisone acetate topical ointment 2.5% in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to hydrocortisone acetate topical ointment 2.5% may be submitted to the agency.

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12690 Filed 5–20–96; 8:45 am]

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[Docket No. 93P–0322]

Determination that Medroxyprogesterone Acetate 100 Milligrams per Milliliter 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 medroxyprogesterone acetate (Depo-Provera®) 100 milligrams per milliliter (mg/mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow sponsors to submit abbreviated new drug applications (ANDA's) for medroxyprogesterone acetate 100 mg/mL.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law 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 (§ 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 August 30, 1993, King & Spalding submitted a citizen petition (Docket No. 93P–0322/CP1) under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether medroxyprogesterone acetate 100 mg/mL 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, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Medroxyprogesterone acetate 100 mg/mL, along with the 400 mg/mL strength, is the subject of approved NDA 12–541 held by the Upjohn Co. (Upjohn). On December 1, 1992, Upjohn withdrew medroxyprogesterone acetate 100 mg/mL from sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that medroxyprogesterone acetate 100 mg/mL was not withdrawn from sale for reasons of safety or effectiveness and will continue to list medroxyprogesterone acetate 100 mg/mL in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to medroxyprogesterone acetate 100 mg/mL may be submitted to the agency.

FDA has also considered the comment submitted by Upjohn, dated November 19, 1993, opposing an FDA determination that medroxyprogesterone acetate 100 mg/mL was withdrawn from the market for reasons other than safety or effectiveness. The comment does not contain any information indicating that the drug was withdrawn for reasons of safety or effectiveness, but rather indicates that Upjohn did not perceive a need to keep medroxyprogesterone