DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0430]

Lilly Research Labs et al.; Withdrawal of Approval of 16 New Drug Applications and 30 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 16 new drug applications (NDAs) and 30 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective November 12, 2002.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 3–188	Eprolin (vitamin E) Capsules.	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 8–317	ACTH Injection (corticotropin for injection USP).	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 8–682	Thytropar (thyrotropin for injection).	Aventis Pharmaceuticals, Inc., 399 Interpace Pkwy., P.O. Box 663, Parsippany, NJ 07054.
NDA 9–766	Meticorten (prednisone) Tablets.	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 12–034	Permitil (fluphenazine hydrochloride (HCl)) Tablets.	Do.
NDA 14–394[1]	Xylocaine (lidocaine), 10% Oral Spray.	AstraZeneca, L.P., 725 Chesterbrook Blvd., Wayne, PA 19087–5677.
NDA 15–874	Alupent (metaproterenol sulfate USP) Tablets, 10 milligrams (mg) and 20 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877.
NDA 17–056	Follutein (chorionic gonadotropin for injection USP) Injection.	Bristol-Myers Squibb Pharmaceutical Research Institute, P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 17–316	Sodium Iodide I–131 Capsules.	CIS Bioindustries, c/o CIS–US, Inc., 101 De Angelo Dr., Bedford, MA 01730.
NDA 17–571	Alupent (metaproterenol sulfate) Syrup, 10 mg/5 milliliters (mL).	Boehringer Ingelheim Pharmaceuticals, Inc.
NDA 17–695	Antuitrin-S (chorionic gonadotropin), 5,000 units.	Parke-Davis, 201 Tabor Rd., Morris Plains, NJ 07950.
NDA 17–726	Asellacrin (somatropin) Injection.	Serono, Inc., 100 Longwater Circle, Norwell, MA 02061.
NDA 18–821	Reglan (metoclopramide) Syrup.	A.H. Robbins, c/o Wyeth-Ayerst Research, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 19–368	Moctanin (monoctanoin).	Ethitek Pharmaceuticals Co., 3 Court of Overlook Bluff, Northbrook, IL 60062.
NDA 20–200	Nalbuphine HCl Injection, 1.5 mg/mL.	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064–3537.
NDA 20–417	FemPatch (estradiol) Transdermal System.	Parke-Davis, 2800 Plymouth Rd., Ann Arbor, MI 48105.
ANDA 60–004	V-Cillin K (penicillin V potassium USP) Powder for Oral Solution, 125 mg/5 mL and 250 mg/5 mL.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
ANDA 60–463	Garamycin (gentamicin sulfate ointment USP) Ointment, 0.1%.	Schering Corp.
ANDA 60–781	Penicillin G Potassium Tablets USP.	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504–4310.
ANDA 61–624	Penicillin V Potassium for Oral Solution USP, 125 mg/5 mL and 250 mg/5 mL.	Do.
ANDA 63–017	Cefadroxil Capsules USP, 500 mg.	Purpac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 63–119	Tombramycin Sulfate Injection USP, 10 mg/mL.	AstraZeneca, L.P., 1800 Concord Pike, Wilmington, DE 19803–8355.
ANDA 63–265	Amikacin Sulfate Injection USP.	Abbott Laboratories.
ANDA 63–266	Amikacin Sulfate Injection USP.	Do.
ANDA 63–295	Monocid (cefonicid for injection USP), 1 gram (g) vials.	GlaxoSmithKline, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101–7929.
ANDA 70–125	Propranolol HCl Tablets USP, 10 mg.	Lederle Laboratories, c/o ESI Lederle, P.O. Box 41502, Philadelphia, PA 19101–7929.
ANDA 70–127	Propranolol HCl Tablets USP, 40 mg.	Do.
ANDA 70–629	Ibuprofen Tablets USP, 400 mg.	Do.
ANDA 70–630	Ibuprofen Tablets USP, 600 mg.	Do.
ANDA 70–636	Fentanyl Citrate Injection USP, 0.05 mg/mL.	Abbott Laboratories.
ANDA 70–637	Fentanyl Citrate Injection USP, 0.05 mg/mL.	Do.

Application No.	Drug	Applicant
ANDA 71–065	Ibuprofen Tablets USP, 200 mg.	Lederle Laboratories.
ANDA 72–045	Haloperidol Intensol Oral Concentrate (haloperidol oral solution USP), 2 mg/mL.	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216.
ANDA 72–768	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg/80 mg.	Do.
ANDA 73–528	Loperamide HCl Tablets USP, 2 mg.	Able Laboratories, Inc., l6 Hollywood Court, South Plainfield, NJ 07080–4295.
ANDA 73–590	Lactulose Solution USP, 10 g/15 mL.	Roxane Laboratories.
ANDA 74–638	Iopamidol Injection USP, 61%.	Abbott Laboratories.
ANDA 74–662	Ranitidine Tablets USP, 150 mg and 300 mg.	Boehring Ingelheim Corp., c/o Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216–6532.
ANDA 75–230	Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL.	Bedford Labs, 300 Northfield Rd., Bedford, OH 44146.
ANDA 75–249	Midazolam HCl Injection, 5 mg (base)/mL.	Do.
ANDA 75–455	Midazolam HCl Injection 5 mg (base)/mL.	Ben Venue Laboratories, Inc., 300 Northfield Rd., Bedford, OH 44146.
ANDA 80–256	Methyltestosterone Tablets USP, 10 mg and 25 mg.	Eli Lilly and Co.
ANDA 83–799	Imipramine HCl Tablets USP, 25 mg and 50 mg.	Roxane Laboratories.
ANDA 87–743	Roxiprin Tablets (oxycodone and aspirin tablets USP).	Do.
ANDA 89–239	Mannitol Injection USP, 25%.	AstraZeneca, L.P.
ANDA 89–240	Mannitol Injection USP, 25%.	Do.

[1] While NDA 14–394 was named in the FEDERAL REGISTER withdrawal notice of April 30, 1984 (49 FR 18357), this NDA was never withdrawn and remained active until 1999.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective November 12, 2002.

Dated: September 27, 2002.

Janet Woodcock,

Center for Drug Evaluation and Research.

[FR Doc. 02–25882 Filed 10–9–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0407]

Diagnostic X-Ray Field Size; Revocation of Compliance Policy Guide 7133.17

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled ''Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17).'' This CPG is no longer necessary because the agency amended the Diagnostic X-Ray Systems Federal Performance Standard to include the minimum x-ray field size.

DATES: The revocation is effective November 12, 2002.

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, or FAX your request to 301–827–0482.

A copy of the CPG may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the CPG entitled ''Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)'' on October 1, 1980. This CPG addresses the different requirements for minimum field size for spot-film and fluoroscopic modes of operation for fixed source-image receptor distance (SID) fluoroscopic x-ray systems. This CPG includes a statement that such systems that do not have stepless adjustment would be required to provide a minimum field size of 125 square centimeters or less during fluoroscopy and spot-film radiography.

In the **Federal Register** of May 3, 1993 (58 FR 26401), FDA amended the diagnostic X-ray systems Federal performance standard to incorporate a provision for spot-film devices used on fixed SID fluoroscopic systems. Specifically, 21 CFR 1020.31(h)(4)(i) requires that for spot-film devices used on fixed SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square centimeters.

Given the current diagnostic X-ray systems Federal performance standard, FDA is revoking CPG 7133.17, in its entirety, to eliminate unnecessary compliance policy.

II. Electronic Access

Before November 12, 2002, a copy of the CPG may be obtained from the Internet at http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg398–475.html.

Dated: October 1, 2022.

John Marzilli,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–25881 Filed 10–9–02; 8:45 am]

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