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NDA 14–394 was named in the FEDERAL REGISTER withdrawal notice of April 30, 1984 (49 FR 18357), this NDA was never withdrawn and remained active until 1999.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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective November 12, 2002.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]

BILLING CODE 4160–01–S

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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