has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
NDA 19–961	Ganite (gallium nitrate)
ANDA 62–507	Gentamicin Sulfate Injection USP, 10 and 40 milligrams (mg)/milliliter (mL)
ANDA 62–605	Kanamycin Sulfate Injection USP, 500 mg/2 mL and 75 mg/2 mL and 1 gram/3 mL
ANDA 62–819	Clindamycin Phosphate Injection USP, 150 mg/mL
ANDA 62–852	Clindamycin Phosphate Injection USP, 150 mg/mL
ANDA 70–046	Dopamine Hycrochloride Injection USP, 40 mg/mL
ANDA 70–047	Dopamine Hycrochloride Injection USP, 80 mg/mL
ANDA 70–078	Furosemide Injection USP, 10 mg/mL
ANDA 70–137	Propranolol Hydrochloride Injection USP, 1 mg/mL
ANDA 70–623	Metoclopramide Injection USP, 5 mg/mL
ANDA 70–633	Nitroglycerin Injection USP, 5 mg/mL
ANDA 70–696	Verapamil Hydrochloride Injection USP, 2.5 mg/mL
ANDA 70–801	Haloperidol Lactate Injection USP, 5 mg/mL
ANDA 70–841	Methyldopate Hydrochloride Injection USP, 50 mg/mL
ANDA 70–864	Haloperidol Injection USP, 5 mg/mL
ANDA 71–671	Naloxone Hydrochloride Injection USP, 0.02 mg/mL
ANDA 71–681	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
ANDA 71–682	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
ANDA 71–754	Droperidol Injection USP, 2.5 mg/mL
ANDA 71–755	Droperidol Injection USP, 2.5 mg/mL
ANDA 87–591	Hydroxyzine Hydrochloride Injection USP, 25 mg/mL
ANDA 87–593	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL
ANDA 87–595	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL
ANDA 88–239	Heparin Sodium Injection USP, 1,000 Units/mL
ANDA 88–457	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88–458	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88–459	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88–460	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88–517	Hydralazine Hydrochloride Injection USP, 20 mg/mL
ANDA 88–519	Phenytoin Sodium Injection USP, 50 mg/mL
ANDA 88–530	Procainamide Hydrochloride Injection USP, 100 mg/mL
ANDA 88–531	Procainamide Hydrochloride Injection USP, 500 mg/mL
ANDA 88–580	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88–581	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88–749	Aminophylline Injection USP, 25 mg/mL
ANDA 88–767	Fluorouracil Injection USP, 50 mg/mL
ANDA 88–960	Trimethobenzamide Hydrochloride Injection USP, 100 mg/mL
ANDA 89–251	Prochlorperazine Edisylate Injection USP, 5mg/mL
ANDA 89–434	Flourouracil Injection USP, 50 mg/mL

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 July 21, 1999.

Dated: June 7, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–15581 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1818]

Steris Laboratories, Inc.; Withdrawal of Approval of 55 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 55 abbreviated new drug applications (ANDA's). Steris Laboratories, Inc., notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: JULY 21, 1999.

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

SUPPLEMENTARY INFORMATION: Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. Steris Laboratories, Inc., has also, by its request, waived its opportunity for a hearing.

ANDA No.	Drug
40–043	Edrophonium Chloride Injection USP, 10 milligrams (mg)/milliliter (mL)
40–044	Edrophonium Chloride Injection USP, 10 mg/mL
62–788	Neomycin and Polymyxin B Sulfate and Gramicidin Ophthalmic Solution
62–900	Clindamycin Phosphate Injection USP, 150 mg/mL
63–079	Clindamycin Phosphate Injection USP, 150 mg/mL
70–019	Furosemide Injection USP, 10 mg/mL
70–170	Metronidazole Injection, 500 mg
70–604	Furosemide Injection USP, 10 mg/mL
70–713	Haloperidol Injection USP, 5 mg/mL
70–744	Haloperidol Injection USP, 5 mg/mL
70–911	Diazepam Injection, 5 mg/mL (ampule)
70–930	Diazepam Injection USP, 5 mg/mL (syringe)
71–556	Sulfamethoxazole and Trimethoprim for Injection Concentrate USP, 80 mg/mL and 15 mg/mL
71–339	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
73–488	Fentanyl Citrate Injection USP, 50 micrograms (mcg)/mL
73–520	Droperidol Injection USP, 2.5 mg/mL
73–521	Droperidol Injection USP, 2.5 mg/mL
73–523	Droperidol Injection USP, 2.5 mg/mL
74–228	Etoposide Injection, 20 mg/mL
83–362	Prednisolone Tebutate Suspension, 20 mg/mL
83–702	Dexamethasone Sodium Phosphate Injection USP, 4 mg/mL
83–767	Prednisolone Acetate Suspension, 40 mg/mL
83–820	Brompheniramine Maleate Injection, 100 mg/mL
84–510	Promazine Hydrochloride Injection USP, 25 mg/mL
84–517	Promazine Hydrochloride Injection USP, 50 mg/mL
84–737	Hydrocortisone Sodium Succinate for Injection USP, 250 mg
84–738	Hydrocortisone Sodium Succinate for Injection USP, 100 mg
84–747	Hydrocortisone Sodium Succinate for Injection USP, 500 mg
84–748	Hydrocortisone Sodium Succinate for Injection USP, 1000 mg
84–875	Mersalyl-Theophylline Injection
85–237	Sterile Estrone Suspension USP, 2 mg/mL
85–434	Phenytoin Sodium Injection USP, 50 mg/mL
85–490	Testosterone Propionate Injection, 25 mg/mL and 50 mg/mL
85–594	Amitriptyline Hydrochloride Injection USP, 10 mg/mL
85–599	Testosterone Enanthate Injection USP, 100 mg/mL
85–606	Dexamethasone Sodium Phosphate Injection USP, 24 mg/mL
86–208	Potassium Chloride Injection
86–210	Potassium Chloride Injection
86–386	Nandrolone Phenpropionate Injection USP, 25 mg/mL
86–947	Glycopyrrolate Injection USP, 0.2 mg/mL
86–953	Methylprednisolone Sodium Succinate for Injection, 40 mg
87–030	Methylprednisolone Sodium Succinate for Injection, 125 mg
87–079	Procainamide Hydrochloride Injection USP, 100 mg/mL
87–080	Procainamide Hydrochloride Injection USP, 500 mg/mL
87–460	Mannitol Injection USP, 250 mg/mL
87–488	Nandrolone Phenpropionate Injection USP, 50 mg/mL
88–523	Methylprednisolone Sodium Succinate for Injection, 500 mg
88–524	Methylprednisolone Sodium Succinate for Injection, 1000 mg
88–554	Nandrolone Decanoate Injection, 50 mg/mL
88–772	Corticotropin for Injection USP, 40 units (vial)
89–163	Potassium Chloride for Injection Concentrate USP, 2 milliequivalents (mEq)/mL
89–170	Dexamethasone Ophthalmic Suspension USP, 0.1%
89–171	Tropicamide Ophthalmic Solution USP, 0.5%
89–421	Potassium Chloride Injection USP, 2 mEq/mL
89–606	Prochlorperazine Edisylate Injection USP, 5 mg

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 July 21, 1999

Dated: June 7, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–15660 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1265]

Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products; Draft; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until August 2, 1999, the comment period for the draft standard memorandum of understanding (MOU) entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products'' (draft standard MOU) that States may enter into with FDA. FDA published a notice of availability of the draft standard MOU in the **Federal Register** of January 21, 1999 (64 FR 3301). The agency is taking this action in response to numerous requests for an extension of the comment period.

DATES: Written comments on the draft standard MOU may be submitted by August 2, 1999.

ADDRESSES: Copies of the draft standard MOU are available on the Internet at ''http://www.fda.gov/cder/pharmcomp/default.htm''. Submit written requests for single copies of the draft standard MOU entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Fred Richman, Center for Drug Evaluation and Research (HFD–332), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737, 301–827–7292.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA published a notice announcing the availability of a draft standard MOU entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products'' that States may enter into with FDA. The draft standard MOU describes the responsibilities of the States and FDA in investigating and responding to complaints related to compounded drug products distributed interstate and addresses the interstate distribution of inordinate amounts of compounded drug products. FDA has developed this MOU in consultation with the National Association of Boards of Pharmacy under provisions of the Food and Drug Administration Modernization Act of 1997. Interested persons were given until March 22, 1999, to submit written comments on the draft standard MOU.

In the **Federal Register** of March 23, 1999 (64 FR 13997), FDA extended the comment period on the draft standard MOU to June 1, 1999.

In response to numerous requests, FDA has decided to reopen the comment period on the draft standard MOU until August 2, 1999.

Interested persons may, on or before August 2, 1999, submit to the Dockets Management Branch (address above) written comments on the draft standard MOU. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft standard MOU and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–15582 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Assessment of Factors Influencing the Adequacy of Health Care Services to Children in Foster Care and Other Out-of-Home Placements—New

The Maternal and Child Health Bureau of HRSA is planning to conduct a survey of health care services for children in foster care and other out-of-home care settings in the United States. This project is aimed at identifying the contributing factors affecting the delivery of health care services to these children. A survey will be conducted of Child Welfare, Child Health/MCH, Medicaid and Mental Health agencies in all 50 states, the District of Columbia, and five counties in each of 11 states with county-administered child welfare systems. An additional 10 counties will be surveyed to include the counties with the largest population, bringing the total sample to 65 counties. This survey will obtain information describing the range of health service delivery arrangements currently provided, obtain a comprehensive assessment of the organization and delivery of services, and collect data on what different jurisdictions are doing to improve the delivery of health services to this population.

Estimates of the annualized reporting burden are as follows: