



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

April 27, 1992

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION  
(SP-92-081)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION..... XX Radiopharmaceutical Drug  
Products

Supplementary information: Enclosed for your information is a copy of the  
Summary of Approved Radiopharmaceutical Drug Products.

If you have further questions regarding this correspondence, please contact  
the individual named below.

POINT OF CONTACT: Lloyd Bolling  
TELEPHONE: (301) 504-2327  
FAX (301) 504-3502

*[Handwritten Signature: Wandy L. Miller]*  
Wandy L. Miller, Assistant Director  
for State Agreements Program  
Office of State Programs

Enclosure:  
As stated

9306150301 930503  
PDR COMMS NRCC  
CORRESPONDENCE PDR

*[Handwritten: 9306150301]*

October 1991

# SUMMARY OF FDA APPROVED RADIOPHARMACEUTICAL DRUG PRODUCTS

The firms listed are those which presently hold the NDA for the product, not necessarily the ones that distribute the product or the ones that originally developed the product. There are firms which have acquired other firms or products and are presently transferring the ownership of the NDA's to their own name. Firms may appear which are the NDA holders but do not market the product at this time due to commercial reasons. Those NDA numbers are noted by an asterisk (\*).

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Fluorine F 18 Injection</u>				
17-042*	Fluorine 18 Injection	2/24/72	Medi-Physics	Bone imaging agent to define areas of altered osteogenic activity.
<u>Chronic Phosphate P 32</u>				
17-084	Phosphocol P 32	09/23/74	Mallinckrodt	Treatment of peritoneal or pleural effusions caused by metastatic disease; interstitial treatment of cancer.
10-927*	Phosphotope oral solution, injection	05/02/57	Squibb Diagnostics	Treatment of polycythemia vera, treatment of chronic myelocytic leukemia and chronic lymphocytic leukemia. Used for the palliative treatment of selected patients with multiple areas of skeletal metastases. Diagnostic aid in localizing certain ocular tumors; cerebral tumors at time of surgery in conjunction with a surgical radiation detec- tion probe.

Enclosure 1

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
11-777	Sodium Phosphate P 32 Injection, Capsules*, Solution*	03/04/59	Mallinckrodt	Treatment of polycythemia vera, treatment of chronic myelocytic leukemia and chronic lymphocytic leukemia. Used for the palliative treatment of selected patients with multiple areas of skeletal metastases

Sodium Chromate Cr 51 Injection

13-993	Chromitope Sodium	12/27/71	Squibb Diagnostics	Determination of red blood cell volume or mass, study of red blood cell survival time, evaluation of blood loss.
16-708	Sodium Chromate Cr 51 Inj.	12/23/71	Mallinckrodt	Determination of red blood cell volume or mass, study of red blood cell survival time, evaluation of blood loss.

Chromium Cr 51 Albumin Human

17-835*	Chromalbin	2/23/76	Iso-Tex Diagnostics	Detection and quantitation gastrointestinal protein loss in patients & for placental localization in the investigation of antepartum bleeding & in evaluation for impending amniocentesis.
---------	------------	---------	---------------------	--

Cyanocobalamin Co 57

16-635	Cyanocobalamin Co 57 Capsules	06/21/68	Mallinckrodt	Diagnosis of Addisonian (pernicious) anemia; diagnostic adjunct in defects of intestinal absorption.
16-089	Rubratope-57 & Rubratope 57 Diagnostic Kit	12/21/70	Squibb Diagnostics	Diagnosis of Addisonian (pernicious) anemia; diagnostic adjunct in other defects of intestinal vitamin B12 absorption

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig.</u> <u>Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Cyanocobalamin Co 57 &amp; Co 58</u>				
17-406*	Dicopac Kit	06/10/74	Amersham	Diagnosis of Addisonian (pernicious) anemia; diagnostic adjunct in other defects of intestinal absorption.
<u>Ferrous Citrate Fe 59 Injection</u>				
16-729*	Ferrous Citrate Fe 59 Inj.	12/17/73	Mallinckrodt	Iron turnover studies, which include clearance of iron from plasma, appearance of iron in newly synthesized red blood cells and in various body sites; absorption of iron from the intestine (oral administration).
<u>Cyanocobalamin Co 60</u>				
16-090*	Rubratope 60 Capsules	12/01/71	Squibb Diagnostics	Diagnosis of Addisonian (pernicious) anemia; diagnostic adjunct in other defects of intestinal vitamin B <sub>12</sub> absorption.
<u>Gallium Citrate Ga 67</u>				
17-478	Gallium Citrate Ga 67	5/17/76	The Du Pont Merck Pharmaceutical Co.	May be useful to demonstrate presence and extent of the following malignancies: Hodgkin's disease, lymphomas and bronchogenic carcinoma. Also may be useful as an aid in detecting some acute inflammatory lesions.
17-700*	Gallium Citrate	12/16/77	Medi-Physics	May be useful to demonstrate the presence and extent of Hodgkin's disease or lymphoma.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-655	Neoscan	05/01/78	Medi-Physics	May be useful to demonstrate the presence and extent of Hodgkin's disease, lymphomas and bronchogenic carcinoma.
18-058	Gallium Citrate	02/01/79	Mallinckrodt	May be useful to demonstrate the presence and extent of Hodgkin's disease, lymphoma, bronchogenic carcinoma. Also may be useful as an aid in detecting some acute inflammatory lesions.

Selenomethionine Se 75 Injection

17-047*	Sethotope	05/07/73	Squibb Diagnostics	Pancreatic imaging as an aid in the diagnosis of suspected pancreatic disease.
17-098*	Selenomethionine Se 75	05/07/73	Mallinckrodt	Pancreatic imaging as an aid in the diagnosis of suspected pancreatic disease.
17-257*	Selenomethionine Se 75	11/09/76	Medi-Physics	Pancreatic imaging as an aid in the diagnosis of suspected pancreatic disease.

Krypton Kr 81m Gas Generator

18-088	MPI Krypton Kr 81m Gas Generator	06/12/80	Medi-Physics	Study of pulmonary ventilation.
--------	--	----------	--------------	---------------------------------

Strontium Sr 82 - Rubidium Rb 82 Generator

19-414	Cardiogen-82	12/29/89	Squibb Diagnostics	Myocardial perfusion agent useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction.
--------	--------------	----------	-----------------------	---

E1-5

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig.</u> <u>Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Strontium Nitrate Sr 85</u>				
17-024*	Strotope	07/09/73	Squibb Diagnostics	Bone imaging agent.
<u>Technetium Tc 99m Generator</u>				
17-243	Ultra-TechneKow	11/23/73	Mallinckrodt	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.
17-281*	Technetium Tc 99m Generator (neutron)	08/30/74	The Du Pont Merck Pharmaceutical Co.	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.
16-906*	Technetope II	09/20/74	Squibb Diagnostics	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.
17-339	Minitec II	09/20/74	Squibb Diagnostics	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-693	Technetium Tc 99m Generator	11/15/76	Cintichem	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.
17-771	Technetium Tc 99m Generator (Fission)	11/16/76	The Du Pont Merck Pharma- ceutical Co.	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.

Sodium Pertechnetate Tc 99m Injection

17-267*	Sodium Pertechnetate Tc 99m	10/02/73	Medi-Physics	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.
17-471*	Sodium Pertechnetate Tc 99m	07/18/74	Medi-Physics	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-321*	Sodium Pertechnetate Tc 99m	10/20/76	CIS-US	Brain, thyroid and saliva gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.
17-725	Sodium Pertechnetate Tc 99m	12/30/77	Mallinckrodt, Inc.	Brain, thyroid and salivary gland imaging; placenta localization and blood pool imaging; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; naso lacrimal drainage system imaging.

Technetium Tc 99m Albumin Aggregated Kit

17-833	Macrotec	02/23/76	Squibb Diagnostics	Pulmonary embolus, pulmonary circulation, neoplasm, tuberculosis & emphysema. Used in radionuclide venography as an adjunct in the screening, diagnosis and management of deep vein thrombosis in the lower extremities.
17-842	TechneScan MAA	02/23/76	Mallinckrodt	Scintigraphic imaging of the lungs as an adjunct to other diagnostic procedures whenever information about pulmonary circulation is desired.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-838*	Lungaggregate Reagent	02/23/76	Medi-Physics	Regional pulmonary perfusion, regional pulmonary ischemia, pulmonary embolus, neoplasm and obstructive lung disease.
17-773	MAA Kit	11/16/76	Medi-Physics	Lung imaging as an adjunct in the evaluation of pulmonary perfusion.
17-776	Pulmolite	11/16/76	The Du Pont Merck Pharmaceutical Co.	Lung imaging as an adjunct in the evaluation of pulmonary perfusion.
17-792	Aggregated (Human) Kit	01/19/77	CIS-US (agent for Sorin Biomedica)	Lung imaging as an adjunct in the evaluation of pulmonary perfusion.
17-848*	Technetium Tc99m Lungaggregate	02/23/76	Medi-Physics	Regional pulmonary perfusion, regional pulmonary ischemia, pulmonary embolus, neoplasm and obstructive lung disease.
17-916*	AM Stannous Aggregated	03/20/78	Benedict Nuclear Pharmaceuticals	Lung imaging as an adjunct in the evaluation of pulmonary perfusion.
17-881	MPI MAA Kit	12/30/87	Merck Sharpe & Dohme	Lung imaging as an adjunct in the evaluation of pulmonary perfusion.

Technetium Tc 99m Albumin Colloid Kit

18-263	Microlite	03/25/82	The Du Pont Merck Pharmaceutical Co.	Diagnostic imaging agent for visualization of the functioning elements of the reticuloendothelial (RE) system, of the liver, spleen and bone marrow.
--------	-----------	----------	--------------------------------------	--

E1-9

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Technetium Tc 99m Serum Albumin Kit</u>				
17-775	Technetium 99m HSA Kit	04/01/77	Medi-Physics	Used for imaging the heart blood pool and to assist in the detection of pericardial effusion.
<u>Technetium Tc 99m Disofenin Kit</u>				
18-467	Hepatolite	03/16/82	The Du Pont Merck Pharma- ceutical Co.	Hepatobiliary imaging agent indicated in the diagnosis of acute cholecystitis.
<u>Technetium Tc 99m Etidronate Kit</u>				
17-562*	Technetium Tc 99m Diphos- phonate-Tin Kit	08/05/76	Medi-Physics	Bone imaging agent used to delineate areas of altered osteogenesis.
17-653*	Technetium Tc 99m HEDSPA	11/18/76	Medi-Physics	Skeletal imaging agent used to delineate areas of altered osteogenesis.
17-667*	MPI Stannous Diphosphonate	04/01/77	Medi-Physics	Bone imaging agent used to delineate areas of altered osteogenesis.
<u>Technetium Tc 99m Exametazine Kit</u>				
19-829	Ceretec	12/30/88	Amersham Corporation	An adjunct in the detection of altered regional cerebral perfusion in stroke.
<u>Technetium Tc 99m Lidofenin Kit</u>				
18-489	TechneScan HIDA	10/31/86	Merck Sharp & Dohme	Hepatobiliary imaging agent
<u>Technetium Tc 99m Mebrofenin Kit</u>				
18-963	Choletec	01/21/87	Squibb Diagnostics	Hepatobiliary imaging agent

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Technetium Tc 99m Medronate Kit (Formerly Known as MDP)</u>				
17-972	Osteolite	12/16/77	The Du Pont Merck Pharma- ceutical Co.	May be used as a bone imaging agent to delineate areas of altered osteo- genesis.
18-335	Amer-Scan MDP	08/05/82	Amersham	May be used as a bone imaging agent to delineate areas of altered osteo- genesis.
18-124	AN-MDP	08/28/79	CIS-US	May be used as a bone imaging agent to delineate areas of altered osteo- genesis.
18-035	TechnoScan MDP	11/28/78	Merck Sharp & Dohme	May be used as a bone imaging agent to delineate areas of altered osteo- genesis.
18-107	MDP-Squibb	02/17/81	Squibb Diagnostics	May be used as a bone imaging agent to delineate areas of altered osteo- genesis.
18-141	Technetium Tc 99m Medronate Kit	06/26/79	Medi-Physics	May be used as a bone imaging agent to delineate areas of altered osteo- genesis.

Technetium Tc 99m Mertiatide Kit

19-882	TechnoScan MAG3	06/15/90	Mallinckrodt	Renal imaging agent.
--------	-----------------	----------	--------------	----------------------

Technetium Tc 99m Oxidronate Kit

18-321	Ostescan MDP	02/18/81	Mallinckrodt	Skeletal imaging agent used to demonstrate areas of altered osteogenesis in adults and children.
--------	--------------	----------	--------------	---

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Technetium Tc 99m Pentetate Sodium Kit (Formerly Known as DTPA)</u> <u>(diethylenetriamine pentaacetic acid)</u>				
17-045*	Renotec - Tc 99m Iron Ascorbate-DTPA Kit	07/08/74	Squibb Diagnostics	Kidney imaging agent.
17-264	Technetium 99m DTPA Kit	02/14/74	Medi-Physics	Kidney and brain imaging, assess renal perfusion, estimate glomerular filtration.
17-255	Technetium 99m DTPA Kit	04/15/76	Medi-Physics	Kidney and brain imaging, assess renal perfusion, estimate glomerular filtration.
17-714	AN-DTPA Kit	11/16/76	CIS-US	Kidney and brain imaging, assess renal perfusion, estimate glomerular filtration.
18-511	TechnoScan DTPA Kit	12/29/89	Merck Sharp & Dohme	Kidney and brain imaging, assess renal perfusion, estimate glomerular filtration.

Technetium Tc 99m Pyro- and Trimeta- Phosphates Kit

17-538	TechnoScan PYP Kit	05/28/74	Mallinckrodt	Bone imaging agent used to demonstrate areas of altered osteogenesis and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocar- dial infarction. May be used for gated cardiac blood pool imaging & the detection of sites of gastrointestinal bleeding.
--------	-----------------------	----------	--------------	--

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-680	Phosphotec Kit	10/20/76	Squibb Diagnostics	Bone imaging agent used to delineate areas of altered osteogenesis and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction. May be used for gated cardiac blood pool imaging & the detection of sites of gastrointestinal bleeding.
17-664*	Technetium Tc 99m Poly- phosphate Kit	10/27/76	Medi-Physics	Bone imaging agent used to delineate areas of altered osteogenesis.
17-684	Pyrolite Kit	11/19/76	The Du Pont Merck Pharma- ceutical Co.	Bone imaging agent used to delineate areas of altered osteogenesis and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction. May be used for gated cardiac blood pool imaging & the detection of sites of gastrointestinal bleeding.
19-039	AM-Pyrotec	6/30/87	CIS-US	Bone imaging agent used to delineate areas of altered osteogenesis and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction. May be used for gated cardiac blood pool imaging & the detection of sites of gastrointestinal bleeding.

Technetium Tc 99m Red Blood Cell Kit \*

19-981	Ultratag	6/10/91	Hallinckrodt	Technetium Tc 99m-labeled red blood cells are used for blood pool imaging, including cardiac first pass and gated equilibrium imaging and for detection of sites of gastrointestinal bleeding.
--------	----------	---------	--------------	--

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Technetium Tc 99m Sestamibi Kit</u>				
19-785	Cardiolite	12/21/90	The Du Pont Merck Pharma- ceutical Co.	Myocardial imaging agent used to distinguish norma from abnormal myocardium, and to localize abnormali- ty, in patients with suspected MI. Also for evaluation of myocardial function using first pass technique.

<u>Technetium Tc 99m Sodium Glucoptate Kit</u>				
17-907	Glucoscan	05/25/78	The Du Pont Merck Pharma- ceutical Co.	Used for brain imaging. Indicated for renal per- fusion imaging as an adjunct in the diagnosis, localization and evaluati of kidney disease.
18-272	Technescan Gluceptate	01/27/82	Merck Sharp & Dohme	Used for brain imaging. Indicated for renal per- fusion imaging as an adjunct in the diagnosis, localization and evaluati of kidney disease.

<u>Technetium Tc 99m Succimer Kit</u>				
17-944	Technetium 99m DMSA	05/18/82	Medi Physics	For evaluation of renal parenchymal disorders.

<u>Technetium Tc 99m Sulfur Colloid Injection and Kit</u>				
17-266*	Tc 99m Sulfur Colloid Inj.	04/10/74	Medi-Physics	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
16-923	Tesuloid (kit)	06/10/74	Squibb Diagnostics	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-456*	Tc 99m Sulfur Colloid Inj.	09/24/74	Medi-Physics	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.
17-059	Technecoli (kit)	09/30/74	Mallinckrodt	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.
17-317*	Technetium Tc 99m Sulfur Colloid Inj.	11/18/76	CIS-US	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.
17-784	Technetium Tc 99m Sulfur Colloid Kit	11/18/76	Medi-Physics	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.
17-858	Technetium Tc 99m Sulfur Colloid Kit	04/17/78	CIS-US	Imaging agent for func- tioning of reticuloendo- thelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro- esophageal reflux scinti- graphy, and for the detec- tion of pulmonary aspira- tion of gastric contents.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-724	Technetium Tc 99m Sulfur Colloid Inj.	08/18/78	Mallinckrodt	Imaging agent for functioning of reticuloendothelial cells in the liver, spleen and bone marrow. For esophageal transit studies, gastro-esophageal reflux scintigraphy, and for the detection of pulmonary aspiration of gastric contents.

Technetium Tc 99m Teboroxime Kit

19-928	CardioTec	12/19/90	Squibb Diagnostics	Myocardial imaging agent used to distinguish normal from abnormal myocardium in patients with suspected coronary artery disease using rest/stress technique
--------	-----------	----------	-----------------------	---

Pentetate Indium Disodium In 111

17-707	Indium In 111 DTPA	05/18/82	Medi-Physics	For use in radionuclide cisternography.
--------	-----------------------	----------	--------------	---

Indium In 111 Oxyquinoline Solution

19-044	Indium In 111 Oxyquinoline	12/23/85	Amersham	For radiolabeling autologous leukocytes for use as an adjunct in the detection of inflammatory processes to which leukocytes migrate.
--------	-------------------------------	----------	----------	---

Sodium Iodide I 123 Capsules

17-630	MPI Iodine 123	03/24/76	Medi-Physics	Diagnosis of thyroid function and imaging.
18-671	Iodine I 123	05/28/82	Benedict Nuclear Pharmaceuticals	Diagnosis of thyroid function and imaging.
71-909 (ANDA)	Sodium Iodide I 123 Capsules	02/28/89 (100 uCi)	Mallinckrodt, Inc.	" " "
71-910 (ANDA)	Sodium Iodide I 123 Capsules	02/28/89 (200 uCi)	Mallinckrodt, Inc.	" " "

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Iodohippurate Sodium I 123 Injection</u>				
18-289	Nephroflow	12/28/84	Medi-Physics	Diagnostic aid in determining renal function, renal blood flow, and urinary tract obstruction. & as a renal imaging agent

<u>Iofetamine HCl I 123 Injection</u>				
19-432	Spectamine	12/24/87	Medi-Physics	Brain imaging agent for evaluation of nonlacunar stroke especially when use within 96 hours of onset of focal neurological deficit

<u>Iothalamate Sodium I 125 Injection</u>				
17-279	Glofil-125	02/12/74	Iso-Tex Diagnostics	Evaluation of glomerular filtration in the diagnosis or monitoring of patients renal disease.

<u>Iodinated I 125 Albumin Injection</u>				
17-836*	Jeanatope 125 I	11/13/63	Iso-Tex Diagnostics	Blood and plasma volume determination. Metabolism and turnover studies.
17-844	Radioiodinated Serum Albumin (Human) (IHSA I-125)	02/23/76	Mallinckrodt	Blood and plasma volume determinations. Blood circulation studies.

<u>Xenon Xe 127</u>				
18-536	Xe 127 Gas	10/1/82	Mallinckrodt	Has been shown to be valuable for diagnostic inhalation studies for the evaluation of pulmonary function and for imaging the lungs.

E1-18

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Sodium Iodide I 131</u>				
8-200*	Sodium Iodide I 131 oral solution & caps.	11/23/51	Syncor	Diagnosis of thyroid function, for thyroid imaging. To localize metastases associated with thyroid malignancies. Treatment of hyper- thyroidism and selected cases of carcinoma of the thyroid.
10-929	Iodotope oral solution & caps.	05/02/57	Squibb Diagnostics	Diagnosis of thyroid function, for thyroid imaging. To localize metastases associated with thyroid malignancies. Treatment of hyper- thyroidism and selected cases of carcinoma of the thyroid.
16-515	Sodium Iodide I 131 oral solution	08/18/71	Mallinckrodt	Diagnosis of thyroid function, for thyroid imaging. To localize metastases associated with thyroid malignancies. Treatment of hyper- thyroidism and selected cases of carcinoma of the thyroid.
16-517	Sodium Iodide I 131 capsules	08/20/71	Mallinckrodt	Diagnosis of thyroid function, for thyroid imaging. To localize metastases associated with thyroid malignancies. Treatment of hyper- thyroidism and selected cases of carcinoma of the thyroid.
17-316	Sodium Iodide I 131 capsules	11/09/76	CIS-US (agent for Compagnie Oris Industrie)	Diagnosis of thyroid function, for thyroid imaging. To localize metastases associated with thyroid malignancies.
17-315	Sodium Iodide I 131 Solution Oral	11/16/76	CIS-US (agent for Compagnie Oris Industrie)	Treatment of hyper- thyroidism and selected cases of carcinoma of the thyroid.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
<u>Iodinated I 131 Albumin Aggregated Injection</u>				
17-834*	Albumotope L-S	02/23/76	Squibb Diagnostics	Pulmonary emboli, pulmonary vascular obliteration, congenital heart disease, diffuse pulmonary disorders.
<u>Rose Bengal Sodium I 131 Injection</u>				
16-224*	Robengatope	11/23/71	Squibb Diagnostics	Diagnostic aid for deter- mination of liver function and liver imaging.
<u>Iodinated I 131 Albumin Injection</u>				
17-837	Megatope	02/23/76	Iso-Tex Diagnostics	Blood and plasma volume, cardiac output, cardiac and pul. blood volumes, circulation times, protein turnover, placenta localization, brain and heart imaging.
<u>Iodohippurate Sodium I 131 Injection</u>				
16-666	Hippuran I 131 Inj.	05/24/68	Mallinckrodt	Diagnostic aid in deter- mining renal function, renal blood flow and urinary tract obstruction, & as a renal imaging agent.
15-419	Hipputope	06/25/70	Squibb Diagnostics	Diagnostic aid in deter- mining renal function, renal blood flow and urinary tract obstruction.
17-313	Iodohippurate Sodium I 131 Injection	11/16/76	CIS-US (agent for Sorin Biomedica)	Diagnostic aid in deter- mining renal function, renal blood flow and urinary tract obstruction.
<u>Xenon Xe 133</u>				
17-283*	Xenon Xe 133 Injection (Solution)	10/11/74	The Du Pont Merck Pharma- ceutical Co.	Diagnosis of cardiac abnormalities, cerebral blood flow studies, pul- monary function studies, muscle blood flow studies and skin blood flow.

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
17-284	Xe 133 Gas	10/10/74	The Du Pont Merck Pharma- ceutical Co.	The gas may be used for inhalation studies in the evaluation of pulmonary function, for imaging the lungs, or the assessment of cerebral blood flow.
17-550	Xenon Xe 133 Gas	03/24/76	General Electric	The gas may be used for inhalation studies in the evaluation of pulmonary function, for imaging the lungs or the assessment of cerebral blood flow.
17-256	Xenon Xe 133 Gas	11/09/76	Medi-Physics	The gas may be used for inhalation studies in the evaluation of pulmonary function, for imaging the lungs, or the assessment of cerebral blood flow.
18-327	Xenon Xe 133 Gas	03/09/82	Mallinckrodt	The gas may be used for inhalation studies in the evaluation of pulmonary function, for imaging the lungs, or the assessment of cerebral blood flow.
17-687	Xenon Xe 133 V.S.S. (Ventilation Study System)	11/16/78	Medi-Physics	Study of pulmonary ventilation.

Chlormerodrin Hg 197 Injection

17-269*	Chlormerodrin Hg 197 Inj.	06/03/74	Squibb Diagnostics	Kidney and brain imaging.
---------	------------------------------	----------	-----------------------	---------------------------

Gold Au 198 Injection

10-928*	Aureotope (diag. and therap.)	04/02/57	Squibb Diagnostics	Therapeutic: palliative management of ascites and pleural effusion associated with metastatic malignancies; Diagnostic: liver imaging.
---------	-------------------------------------	----------	-----------------------	--

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig.</u> <u>Approved</u>	<u>Firm</u>	<u>Indication</u>
				<u>Thallous Chloride Tl 201</u>
17-806	Thallous Chloride Tl 201	12/16/77	The Du Pont Merck Pharmaceutical Co.	May be useful in myocardial perfusion imaging and for the diagnosis and localization of myocardial infarction. May have prognostic value regarding survival after onset of symptoms of acute MI to assess site and size of perfusion defect. Also useful for localization of sites of parathyroid hyperactivity.
18-150	Thallous Chloride Tl 201 Injection	10/23/79	Mallinckrodt	May be useful in myocardial perfusion imaging and for the diagnosis and localization of myocardial infarction. May have prognostic value regarding survival after onset of symptoms of acute MI to assess site and size of perfusion defect. Also useful for localization of sites of parathyroid hyperactivity.
18-110	Thallous Chloride Tl 201 Injection	01/29/82	Medi-Physics	May be useful in myocardial perfusion imaging and for the diagnosis and localization of myocardial infarction. May have prognostic value regarding survival after onset of symptoms of acute MI to assess site and size of perfusion defect. Also useful for localization of sites of parathyroid hyperactivity.
18-548	Thallous Chloride Tl 201 Injection	12/30/82	Squibb Diagnostics	Same as above

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
			<u>Potassium Perchlorate</u>	
17-551	Perchloracap Capsules	11/21/74	Mallinckrodt	To minimize the accumula- of pertechnetate Tc 99m in the choroid plexus, the salivary and thyroid glands.

M. Anderson/3478A/03/24/91

0093(Diskette)

NEW NDA

Technetium Tc 99m Red Blood Cell Kit

<u>NDA</u>	<u>Trade Name</u>	<u>Date Orig. Approved</u>	<u>Firm</u>	<u>Indication</u>
19-981	Ultratag	6/10/91	Mallinckrodt	Technetium Tc 99m-labeled red blood cells are used for blood pool imaging, including cardiac first pass and gated equilibrium imaging, and for detection of sites of gastrointestinal bleeding.