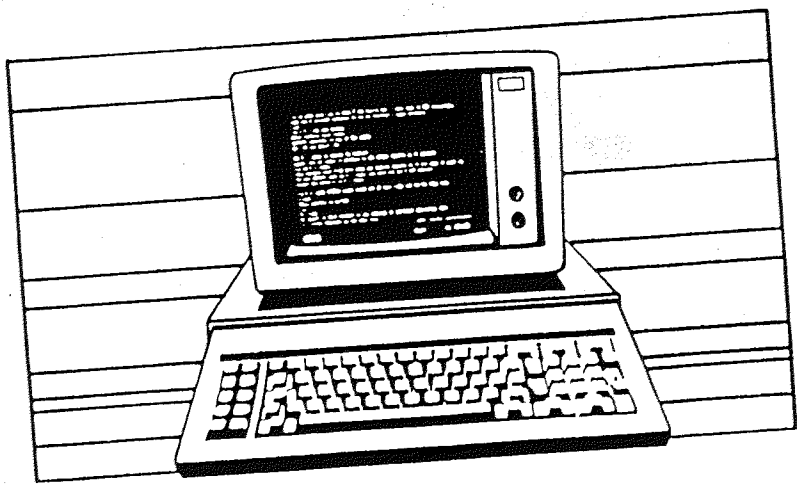
INACTIVE INGREDIENT GUIDE



DIVISION OF
DRUG INFORMATION RESOURCES

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT

JANUARY 1996

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INACTIVE INGREDIENT GUIDE

Purpose The *Inactive Ingredient Guide* contains all inactive ingredients present in approved drug products or conditionally approved drug products currently marketed for human use. The *Guide* is compiled by the Division of Drug Information Resources (DDIR). It provides CDER/CBER Reviewers with information on inactive ingredients in products which have been approved by the Agency. Once an inactive ingredient appears in a currently approved drug product for a particular route of administration, the inactive ingredient would not usually be considered new and may require a less extensive review.

Design The *Inactive Ingredient Guide* has been sorted first alphabetically by ingredient, and then by route of administration and dosage form. Routes of administration and dosage forms are derived from current approved labeling.

Definitions 21 CFR 210.3(b)(8,7, respectively) defines inactive ingredients and active ingredients as follows: "Inactive ingredient means any component other than the active ingredient. Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. The term (active ingredient) includes those components that may undergo chemical change in the manufacture of the drug product and be present in the finished drug product in a modified form intended to furnish the specified activity or effect." As an exception of the CFR definition, inactive ingredients listed in the *Guide* include only those which are present in the final dosage form of the drug product.

Synonyms DDIR maintains a dictionary of all ingredients contained in submissions to CDER. Since many ingredients have synonyms (which do not appear in the *Inactive Ingredient Guide*), it may assist you to contact your Drug Information Officer if you cannot find a particular inactive ingredient.

Proprietary Inactive Ingredients DDIR does not always include the components of proprietary inactive ingredients (e.g., OPACODES). In such situations where components of proprietary inactive ingredients are included, you may have to search for such data under individual component entries.

Warnings The *Inactive Ingredient Guide* lists inactive ingredients specifically intended as such by the manufacturer. Some of these inactive ingredients could also be considered as active ingredients under different circumstances (see 21 CFR 210.3(b)(7,3)). Furthermore, reactants in radiopharmaceutical kits, or inactive ingredients which physically or chemically combine with active ingredients to facilitate drug transport are considered as inactive ingredients for the purposes of this *Guide*.

[Continued]

Contaminants The *Inactive Ingredient Guide* does not represent contaminants found in approved drug products.

Carcinogens and Teratogens If any of the inactive ingredients represented in the *Inactive Ingredient Guide* are proven to be carcinogenic, teratogenic, or embryotoxic, please notify DDIR immediately. DDIR will attempt to relay your concern to each medical officer and pharmacologist reviewer responsible for oversight of other approved drug products which contain the specified inactive ingredient.

CAS Number Many inactive ingredients have Chemical Abstracts Service (CAS) numbers associated with them. These can be found in the column to the right of the inactive ingredient. CAS numbers may be helpful to CDER/CBER Reviewers when initiating computer-assisted searches with the National Library of Medicine's online data bases.

Qualitative NDA Data The next five columns to the right of the CAS number serve to qualify the data presented. The **'NDA CT'** reflects the total number of NDAs in which a particular inactive ingredient currently appears. The **'Last NDA'** specifies which NDA was the most recent one to be approved by the Agency with this inactive ingredient. The **'APPROVAL DATE'** and **'DIV'** specify the approval date and Review Division responsible for evaluating this most recent NDA. The **'POTENCY RANGE'** specifies the minimum and maximum amounts of inactive ingredients for each route of administration and dosage form. In some cases, values in the **'POTENCY RANGE'** column have been collapsed into percentage of the total product in order to integrate data.

Colors The Certification Branch of the Division of Color Technology has designated permanently listed, provisionally listed, and delisted color additives. These appear in the Appendix. Please consult the 21 CFR 74 and 82 for detailed information on uses, restrictions, and tolerances of color additives.

Inactive Ingredient Structures Chemical structures of all inactive ingredients which have been submitted to the Agency are available for review by contacting Rona Sun or Kyung Kim, DDIR Chemists, at 443-3910.

Procedure for Obtaining Further Assistance The Division of Drug Information Resources can also provide you with more specialized searches on the automated data base from which the *Inactive Ingredient Guide* is generated. For assistance in using the *Guide*, to schedule a presentation on the *Guide*, or for a more detailed search, contact your DDIR Drug Information Officer on the following page or Mark Askine at 443-0500.

DIVISION OF DRUG INFORMATION RESOURCES
DRUG INFORMATION OFFICERS

Division of Cardio-Renal Drug Products, HFD-110	Diane Centeno-Deshields, R.Ph.
Division of Neuropharmacological Drug Products, HFD-120	Diane Centeno-Deshields, R.Ph.
Division of Oncologic Drug Products, HFD-150	Sharon Brownewell
Division of Medical Imaging, Surgical, and Dental Products, HFD-160	Herbert Thornton, R.Ph.
Division of Anesthesic, Critical Care, and Addiction Drug Products, HFD-170	Mary Guilderson
Division of Gastrointestinal and Coagulation Drug Products, HFD-180	Richard Lipov, R.Ph
Division of Metabolism and Endocrine Drug Products, HFD-510	Ronald Brown, R.Ph.
Division of Anti-Infective Drug Products, HFD-520	Mark W. Askine, R.Ph.
Division of Antiviral Drug Products, HFD-530	Lee Anne Parsons
Division of Dermatologic and Ophthalmologic Drug Products, HFD-540	Mark W. Askine, R.Ph
Division of Anti-Inflammatory, Analgesic, and Dental Drug Products, HFD-550	Mary Guilderson
Division of Pulmonary Drug Products, HFD-570	Sharon Brownewell
Division of Generic Drugs, HFD-600	Janet Anderson, R.Ph.

All DDIR Drug Information Officers can be contacted at 443-0500 and are located in Room 218 of the Chapman Building.

INACTIVE INGREDIENT FIELD DESCRIPTION

INGREDIENT ROUTE/DOSAGE FORM	CAS#
ACACIA	009000015
BUCCAL/SUBLINGUAL; TABLET	
ORAL; CAPSULE	
ORAL; CAPSULE, SUSTAINED ACTION	
ORAL; POWDER	

Ingredient Chemical substance added to enhance formulation of given dosage forms. Component of product other than active ingredient.

Route/Dosage Form Formulation intended for the specified route of administration or site of application.

CAS# Registry number assigned to a compound by Chemical Abstracts Service on a random basis.

NDA COUNT	LAST NDA	APPROVAL DATE	DIVISION	POTENCY RANGE
2	N85125	02/02/77	600	4.0 - 9.1 MG
1	N85296	04/01/77	600	
1	N17078	08/02/76	120	0.01 - 0.7 MG
1	N16640	08/03/73	510	21.0%

NDA Count Reflects total number of approved NDAs in which a particular inactive ingredient currently appears.

Last NDA Specifies which NDA was the most recent one to be approved by the Agency with this active ingredient.

Approval Date and DIV Specifies the approval date and the Review Division responsible for evaluating this most recent NDA.

Potency Range Specifies the minimum and maximum amounts of inactive ingredients for each route/dosage form.

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ACACIA	009000015					
BUCCAL/SUBLINGUAL; TABLET		1				
ORAL; CAPSULE		1				
ORAL; CAPSULE, SUSTAINED ACTION		1				
ORAL; POWDER		1				
ORAL; POWDER, FOR RECONSTITUTION		2		03/08/88	600	
ORAL; SYRUP		1				
ORAL; TABLET		113		09/29/95	600	0.03GM
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		2		07/29/92	600	3.22MG - 80.0MG
ORAL; TABLET, COATED		51		02/25/92	600	0.02MG - 156.0MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
ORAL; TABLET, FILM COATED		7		03/15/83	600	0.04MG - 0.08MG
ORAL; TABLET, REPEAT ACTION		2		03/31/81	UNK	11.542MG
ORAL; TABLET, SUSTAINED ACTION		13		01/04/95	600	2.0MG - 34.4MG
ORAL-21; TABLET		2		10/01/76	510	1.26MG
ORAL-28; TABLET		4		03/29/76	510	1.26MG
ACACIA MUCILAGE	008047389					
ORAL; TABLET, COATED		1				
ACETIC ACID						
IM - IV - SC; INJECTION		1				
IM - SC; INJECTION		1				
INTRAMUSCULAR; INJECTION		3		07/09/80	510	
INTRAVENOUS; INJECTION		10		07/31/90	600	0.046%
IV(INFUSION); INJECTION		9		03/25/94	160	0.027% - 0.44%
OPHTHALMIC; POWDER, FOR RECONSTITUTION		1				
OPHTHALMIC; SOLUTION		1				
SUBCUTANEOUS; INJECTION		1				
TOPICAL; SOLUTION		1				
TOPICAL; SPONGE		1				
ACETIC ACID, GLACIAL	000064197					
IM - IV - SC; POWDER, FOR INJECTION SOLUTION		1				
IM - IV; INJECTION		5		05/02/88	600	0.135% - 0.25%
IM - IV; POWDER, FOR INJECTION SOLUTION		1				
IM - SC; INJECTION		7		04/14/95	600	0.01% - 0.48%
IM - SC; INJECTION, SUSTAINED ACTION		1				
INTRA-ARTICULAR; INJECTION		3		05/07/78	600	
INTRAMUSCULAR; INJECTION		9		05/02/88	600	0.006% - 0.0442%
INTRASYNOVIAL; INJECTION		3		05/07/78	600	
INTRAVENOUS; INJECTION		13		03/17/94	UNK	0.01% - 0.225%
IRRIGATION; SOLUTION		1				
IV(INFUSION); INJECTION		27		10/27/95	510	0.12% - 0.435%
IV(INFUSION); POWDER, FOR INJECTION SOLUTION		1				
IV(INFUSION); SOLUTION, INJECTION		1				
NASAL; SOLUTION		1				
NASAL; SPRAY, METERED		1				
OPHTHALMIC; SOLUTION		1				
ORAL; CAPSULE, HARD GELATIN		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ACETIC ACID, GLACIAL	000064197					
ORAL; CONCENTRATE		2		12/16/85	600	0.075% - 0.1%
ORAL; SOLUTION, ELIXIR		1				
OTIC; SOLUTION		1				
OTIC; SUSPENSION		2		11/06/85	600	0.36%
SUBCUTANEOUS; INJECTION		2		06/12/91	510	0.2%
ACETIC ANHYDRIDE	000108247					
ORAL; TABLET, SUSTAINED ACTION		1				
ACETONE SODIUM BISULFITE	000540921					
DENTAL; INJECTION		1				
INHALATION; SOLUTION		2		06/30/81	600	0.4% - 0.50034%
NERVE BLOCK; INJECTION		3		11/15/79	600	0.1% - 0.2%
ACETYL TRIBUTYL CITRATE						
ORAL; CAPSULE, ENTERIC COATED PELLETS		1				
ORAL; CAPSULE, SUSTAINED ACTION		1				
ORAL; TABLET, ENTERIC COATED PARTICLES		1				
ORAL; TABLET, SUSTAINED ACTION		2		01/10/92	110	2.0MG - 9.0MG
ACETYLATED MONOGLYCERIDES						
INTRAVENOUS; INJECTION		1				
ORAL; CAPSULE, SUSTAINED ACTION		1				
ORAL; TABLET		33		02/27/91	600	0.04MG - 2.7MG
ORAL; TABLET, COATED		2		04/26/78	600	
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		2		03/29/82	600	2.92MG - 5.17MG
ORAL; TABLET, FILM COATED		10		02/02/87	600	0.04MG - 2.1MG
ORAL; TABLET, SUSTAINED ACTION		3		05/14/85	UNK	
ACETYLCYSTEINE	000616911					
INHALATION; SOLUTION		4		11/22/88	600	
ACRYLATES COPOLYMER						
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
ADCOTE 72A103						
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
AEROSIL 380						
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
AEROSIL-200						
ORAL; TABLET		20		08/17/88	600	0.1MG - 9.0MG
ORAL; TABLET, FILM COATED		2		02/02/87	600	3.6MG - 7.2MG
AEROTEX RESIN 3730						
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
AIR						
INHALATION; GAS		3		10/01/82	160	
ALBUMIN AGGREGATED						
INTRAVENOUS; INJECTION		5		12/30/87	160	0.025%
ALBUMIN COLLOIDAL						
INTRAVENOUS; POWDER, FOR INJECTION SOLUTION		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ALBUMIN HUMAN	009006535					
INTRAVENOUS; INJECTION		9		12/28/90	510	0.05% - 1.2%
INTRAVENOUS; POWDER, FOR INJECTION SOLUTION		1				
IV(INFUSION); INJECTION		1				
ALCOHOL	000064175					
DENTAL; SOLUTION		4		12/28/95	600	10.0% - 12.15%
IM - IV; INJECTION		21		01/29/93	600	8.55% - 11.0%
IM - IV; SOLUTION, INJECTION		1				
INHALATION; AEROSOL, METERED		5		12/28/84	UNK	30.0% - 38.0%
INHALATION; SOLUTION		1				
INTRAMUSCULAR; INJECTION		1				
INTRAVENOUS; INJECTION		3		02/10/94	600	6.8% - 30.5%
IV - SC; INJECTION		1				
IV(INFUSION); INJECTION		8		08/30/95	600	0.61% - 32.9%
IV(INFUSION); SOLUTION, INJECTION		2		12/31/86	110	10.0% - 30.0%
OPHTHALMIC; SOLUTION		1				
ORAL; AEROSOL SPRAY		1				
ORAL; CONCENTRATE		13		08/30/91	600	0.019% - 71.6%
ORAL; SOLUTION		28		11/17/95	530	0.23% - 30.0%
ORAL; SOLUTION, ELIXIR		23		04/29/93	600	5.0% - 20.4%
ORAL; SUSPENSION		18		09/15/95	180	0.0000067% - 7.25%
ORAL; SYRUP		35		10/28/94	600	0.5% - 7.5%
RECTAL; SUSPENSION		2		11/17/86	600	
TOPICAL; AEROSOL SPRAY		1				
TOPICAL; GEL		2		06/18/90	UNK	52.0%
TOPICAL; LOTION		2		07/03/85	600	71.0% - 80.5%
TOPICAL; SOLUTION		15		02/27/95	600	33.0% - 83.0%
TRANSDERMAL; FILM, CONTROLLED RELEASE		3		09/29/95	510	
VAGINAL; EMULSION, CREAM		1				
ALCOHOL, DEHYDRATED	000064175					
IM - IV; INJECTION		7		10/13/87	600	0.01% - 10.0%
IM - IV; POWDER, FOR INJECTION SOLUTION		1				
INHALATION; AEROSOL, METERED		4		04/23/82	UNK	1.0% - 34.548%
INTRAMUSCULAR; INJECTION		2		11/30/89	UNK	10.0%
INTRAVASCULAR; INJECTION		1				
INTRAVENOUS; INJECTION		6		07/17/95	600	3.0% - 50.0%
IV(INFUSION); INJECTION		12		08/30/95	600	10.0% - 80.0%
IV(INFUSION); POWDER, FOR INJECTION SOLUTION		1				
IV(INFUSION); SOLUTION, INJECTION		1				
NASAL; AEROSOL SPRAY		1				
NASAL; AEROSOL, METERED		1				
OPHTHALMIC; SOLUTION		2		10/11/88	600	0.5%
ORAL; CONCENTRATE		5		11/30/94	600	0.00003% - 7.37%
ORAL; SOLUTION		5		07/14/95	530	0.1% - 24.9%
ORAL; SOLUTION, ELIXIR		6		01/25/82	600	12.0% - 20.0%
ORAL; SUSPENSION		8		06/18/87	600	0.26% - 1.0%
ORAL; SYRUP		19		11/22/85	600	5.0% - 7.0%

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INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ALCOHOL, DEHYDRATED	000064175					
TOPICAL; GEL		4		01/29/93	600	20.0% - 94.7808%
TOPICAL; SOLUTION		5		09/28/90	600	55.0% - 77.0%
TOPICAL; SWAB		1				
ALCOHOL, DENATURED	008024451					
DENTAL; GEL		1				
DENTAL; PASTE		1				
TOPICAL; AEROSOL		1				
TOPICAL; EMULSION, AEROSOL FOAM		1				
TOPICAL; GEL		3		10/26/84	UNK	75.35% - 96.9385%
TOPICAL; SOLUTION		5		01/11/91	600	44.0% - 60.16%
TOPICAL; SWAB		2		07/30/93	600	75.0%
ALCOHOL, DILUTED	008000166					
IM - IV; INJECTION		1				
ORAL; SOLUTION		1				
ORAL; SOLUTION, ELIXIR		2		03/16/79	600	6.5126%
ORAL; SUSPENSION		1				
ORAL; SYRUP		3		08/21/78	600	0.5% - 1.5%
TOPICAL; AEROSOL SPRAY		1				
TOPICAL; POWDER, FOR RECONSTITUTION		1				
ALGINIC ACID	009005327					
OPHTHALMIC; DRUG DELIVERY SYSTEM		1				
OPHTHALMIC; SUPPOSITORY, INSERT, CONTROLLED RELEASE		1				
ORAL; CAPSULE		2		05/14/86	600	17.0MG
ORAL; TABLET		22		12/29/94	110	0.07MG - 30.0MG
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		3		06/28/89	600	150.0MG - 400.0MG
ORAL; TABLET, COATED		1				
ORAL; TABLET, FILM COATED		3		09/03/80	600	16.804MG - 52.8MG
ORAL; TABLET, SUSTAINED ACTION		1				
ALKYL AMMONIUM SULFONIC ACID BETAINE						
TOPICAL; SPONGE		1				
ALKYL ARYL SODIUM SULFONATE						
TOPICAL; SUSPENSION, SHAMPOO		1				
ALLANTOIN	000097596					
TOPICAL; GEL		1				
VAGINAL; EMULSION, CREAM		1				
ALTHEA						
ORAL; SUSPENSION		1				
ALUMINUM ACETATE	000139128					
OTIC; SOLUTION		1				
TOPICAL; EMULSION, CREAM		1				
TOPICAL; SHAMPOO		1				
ALUMINUM HYDROXIDE	001302290					
TOPICAL; EMULSION, CREAM		4		12/22/87	600	5.0%
TOPICAL; OINTMENT		2		10/10/85	600	

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ALUMINUM HYDROXIDE - SUCROSE, HYDRATED						
TOPICAL; EMULSION, CREAM		1				
ALUMINUM HYDROXIDE GEL	012040594					
TOPICAL; EMULSION, CREAM		4		01/29/93	600	0.3% - 1.0%
ALUMINUM HYDROXIDE GEL F 500						
TOPICAL; EMULSION, CREAM		2		10/08/85	600	2.0%
ALUMINUM HYDROXIDE GEL F 5000						
TOPICAL; EMULSION, CREAM		2		10/08/85	600	3.0%
ALUMINUM HYDROXIDE GEL, DRIED	008012633					
ORAL; TABLET		1				
ALUMINUM OXIDE	001344281					
ORAL; TABLET		1				
ALUMINUM POLYESTER						
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
ALUMINUM POTASSIUM SULFATE						
VAGINAL; SUPPOSITORY		1				
ALUMINUM SILICATE	012141467					
ORAL; TABLET		1				
ORAL; TABLET, SUSTAINED ACTION		1				
TOPICAL; SUSPENSION, SHAMPOO		1				
ALUMINUM STARCH OCTENYLSUCCINATE						
TOPICAL; EMULSION, CREAM		1				
ALUMINUM STEARATE	007047849					
ORAL; TABLET		1				
ORAL; TABLET, SUSTAINED ACTION		1				
TOPICAL; EMULSION, CREAM		3		10/29/93	UNK	
TOPICAL; OINTMENT		2		12/17/90	UNK	
ALUMINUM SULFATE	010043013					
OTIC; SOLUTION		2		02/25/94	600	
TOPICAL; EMULSION, CREAM		3		09/28/92	600	
ALZAMER-50						
ORAL; TABLET, SUSTAINED ACTION		1				
AMBERLITE	009002191					
ORAL; CAPSULE		1				
ORAL; TABLET		9		12/21/90	600	1.0MG - 12.0MG
ORAL; TABLET, COATED		1				
ORAL; TABLET, FILM COATED		1				
AMERCHOL L101						
TOPICAL; EMULSION, CREAM		5		08/25/89	UNK	1.0% - 5.0%
AMERCHOL-CAB	008029047					
OPHTHALMIC; OINTMENT		2		12/03/86	600	
AMMONIA	007664417					
INHALATION; LIQUID		1				
AMMONIA SOLUTION	008007576					
ORAL; SUSPENSION		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
AMMONIUM ACETATE	000631618					
INTRAMUSCULAR; INJECTION		3		01/27/95	600	0.4%
INTRAVENOUS; INJECTION		3		01/27/95	600	0.4%
AMMONIUM CALCIUM ALGINATE						
ORAL; TABLET		1				
AMMONIUM CHLORIDE	012125029					
ORAL; TABLET		6		06/09/87	600	2.4MG - 4.2MG
AMMONIUM HYDROXIDE						
INTRAVENOUS; INJECTION		1				
ORAL; CAPSULE		4		05/16/95	600	
SUBCUTANEOUS; INJECTION		1				
AMMONIUM PHOSPHATE, DIBASIC	007783280					
ORAL; TABLET		3		11/02/87	600	0.4MG
AMMONIUM SALT OF C-12-C-15 LINEAR PRIMARY ALCOHOL ETHOXYLATE						
TOPICAL; SPONGE		1				
AMMONIUM SULFATE	007783202					
IM - IV; POWDER, FOR INJECTION SOLUTION		1				
INTRAVENOUS; SUSPENSION, INJECTION		1				
IV(INFUSION); POWDER, FOR INJECTION SOLUTION		1				
AMMONYX						
TOPICAL; EMULSION, AEROSOL FOAM		1				
TOPICAL; SOLUTION		1				
TOPICAL; SPONGE		1				
AMPHOTERIC-2						
TOPICAL; SUSPENSION, SHAMPOO		1				
AMPHOTERIC-6						
TOPICAL; EMULSION, CREAM		1				
ANETHOLE	004180238					
DENTAL; SOLUTION		1				
ORAL; SOLUTION		1				
ORAL; SOLUTION, ELIXIR		5		10/03/83	600	0.003%
ANIDRISORB 85/70						
ORAL; CAPSULE, SOFT GELATIN		2		04/20/95	UNK	30.045MG - 123.0MG
ANISE EXTRACT	000104461					
ORAL; SOLUTION, ELIXIR		2		03/26/76	600	
ANISE OIL	008007703					
ORAL; PASTILLE		1				
ORAL; SOLUTION, ELIXIR		2		12/16/83	600	
ORAL; SUSPENSION		1				
ANISE, STAR						
ORAL; SOLUTION, ELIXIR		1				
ANOXID SBN						
TOPICAL; EMULSION, CREAM		2		10/31/94	600	0.15625%
ANTIFOAM	008051089					
ORAL; SUSPENSION		1				
TOPICAL; LOTION		2		07/16/74	600	0.01% - 0.031%

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ANTIFOAM DC						
ORAL; POWDER, FOR RECONSTITUTION		1				
ANTIPYRINE	000060800					
OPHTHALMIC; SOLUTION		1				
AQUACOAT						
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		1				
AQUACOAT ECD						
ORAL; TABLET, FILM COATED		2		10/03/90	600	
AQUAPHOR	008029150					
TOPICAL; EMULSION, CREAM		1				
TOPICAL; OINTMENT		1				
ARGININE						
IM - IV; INJECTION		3		03/31/92	600	
INTRAVENOUS; POWDER, FOR INJECTION SOLUTION		1				
IV(INFUSION); INJECTION		3		11/07/95	600	0.78% - 1.56%
ARLATONE 289						
TOPICAL; EMULSION, CREAM		1				
ASCORBIC ACID	000050817					
CAUDAL BLOCK; INJECTION		1				
EPIDURAL; INJECTION		1				
IM - IV; INJECTION		2		07/25/74	600	0.2%
INHALATION; AEROSOL, METERED		7		12/28/84	UNK	0.1% - 0.24518%
INHALATION; SOLUTION		11		06/13/91	600	0.02% - 0.038%
INTRAMUSCULAR; INJECTION		5		04/15/88	600	0.1% - 0.2%
INTRAVENOUS; INJECTION		6		03/09/88	600	
INTRAVENOUS; POWDER, FOR INJECTION SOLUTION		1				
IV(INFUSION); INJECTION		3		02/16/89	600	
IV(INFUSION); POWDER, FOR INJECTION SOLUTION		2		10/27/83	600	
NERVE BLOCK; INJECTION		1				
ORAL; CAPSULE		1				
ORAL; CONCENTRATE		5		04/27/83	600	0.05% - 0.2%
ORAL; SUSPENSION, SUSTAINED ACTION		1				
ORAL; SYRUP		2		11/15/82	600	
ORAL; TABLET		6		08/29/88	600	1.0MG - 28.44MG
ORAL; TABLET, FILM COATED		1				
RECTAL; SUPPOSITORY		1				
SUBCUTANEOUS; INJECTION		1				
ASCORBYL PALMITATE	000137666					
ORAL; CAPSULE		1				
ORAL; TABLET		1				
RECTAL; SUPPOSITORY		5		08/14/87	600	
TOPICAL; EMULSION, CREAM		1				
ASPARTAME	053906697					
ORAL; GRANULE, EFFERVESCENT		1				
ORAL; POWDER		1				
ORAL; POWDER, FOR RECONSTITUTION		2		12/23/91	520	0.16% - 1.05%
ORAL; SYRUP		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
ASPARTAME	053906697					
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		3		11/16/94	UNK	5.41MG - 40.0MG
ASPARTIC ACID	000056848					
IV(INFUSION); INJECTION		2		02/18/94	180	0.4% - 0.68%
BALSAM CANADA	008007474					
TOPICAL; LOTION		1				
BALSAM, FIR						
TOPICAL; OIL		1				
BARIUM SULFATE	007727437					
INTRAUTERINE; SUPPOSITORY, INSERT, CONTROLLED RELEASE		1				
BEESWAX						
ORAL; CAPSULE, SOFT GELATIN		2		11/22/95	150	7.579MG - 15.16MG
ORAL; CAPSULE, SUSTAINED ACTION		1				
ORAL; TABLET		16		09/19/89	UNK	0.01MG - 0.1MG
ORAL; TABLET, COATED		11		12/20/82	600	0.02MG - 0.53MG
TOPICAL; EMULSION, CREAM		4		06/30/92	600	1.0%
TOPICAL; OINTMENT		2		12/17/90	UNK	5.0%
BEESWAX, SYNTHETIC						
TOPICAL; EMULSION, CREAM		1				
BENTONITE	001302789					
ORAL; CAPSULE		1				
ORAL; SUSPENSION		2		10/17/90	600	0.45%
ORAL; TABLET		1				
TOPICAL; SUSPENSION, SHAMPOO		3		01/10/91	600	2.1%
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
VAGINAL; SUPPOSITORY		1				
BENZALDEHYDE	000100527					
ORAL; SUSPENSION		1				
BENZALKONIUM CHLORIDE	008001545					
INHALATION; SOLUTION		6		05/28/93	600	0.01% - 0.025%
INTRA-ARTICULAR; INJECTION		1				
INTRABURSAL; INJECTION		1				
INTRADERMAL; INJECTION		1				
INTRALESIONAL; INJECTION		1				
INTRAMUSCULAR; INJECTION		1				
NASAL; SOLUTION		1				
NASAL; SPRAY		1				
NASAL; SPRAY, METERED		10		10/20/95	UNK	0.01% - 0.02%
OPHTHALMIC; GEL		1				
OPHTHALMIC; OINTMENT		1				
OPHTHALMIC; SOLUTION		77		09/29/95	600	0.00004% - 10.0%
OPHTHALMIC; SUSPENSION		28		09/13/95	600	0.001% - 0.025%
OTIC; SOLUTION		4		01/16/85	600	0.01% - 0.02%
TOPICAL; LOTION		2		03/28/73	600	0.1%
TOPICAL; SHAMPOO		1				
TOPICAL; SOLUTION		2		04/11/74	600	0.01%

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
BENZENESULFONIC ACID SOLUTION						
INTRAVENOUS; INJECTION		1				
INTRAVENOUS; SOLUTION, INJECTION		1				
IV(INFUSION); INJECTION		1				
BENZETHONIUM CHLORIDE	000121540					
IM - IV; INJECTION		8		07/16/81	600	0.01%
INTRAMUSCULAR; INJECTION		1				
INTRAVENOUS; POWDER, FOR INJECTION SOLUTION		1				
IV(INFUSION); INJECTION		1				
NASAL; SPRAY, METERED		1				
OPHTHALMIC; POWDER, FOR RECONSTITUTION		1				
OPHTHALMIC; SOLUTION		1				
OTIC; SOLUTION		6		10/31/94	600	0.02%
BENZODODECINIUM BROMIDE	007281041					
OPHTHALMIC; SOLUTION		1				
BENZOIC ACID	000065850					
IM - IV; INJECTION		14		01/29/93	600	0.2% - 5.0%
INTRAMUSCULAR; INJECTION		1				
IRRIGATION; SOLUTION		1				
IV(INFUSION); INJECTION		1				
ORAL; SOLUTION		8		04/24/91	120	0.1%
ORAL; SOLUTION, ELIXIR		4		10/10/86	600	0.1%
ORAL; SUSPENSION		3		08/28/81	110	0.1%
ORAL; SYRUP		8		01/17/89	600	0.1%
ORAL; TABLET, COATED		1				
TOPICAL; EMULSION, CREAM		4		09/13/95	UNK	0.2%
TOPICAL; LOTION		1				
TOPICAL; SUPPOSITORY		2		04/26/93	520	
VAGINAL; EMULSION, CREAM		4		01/04/95	600	0.1% - 0.2%
VAGINAL; SUPPOSITORY		1				
BENZOIN	009000059					
ORAL; CAPSULE		1				
ORAL; CAPSULE, SUSTAINED ACTION		1				
BENZYL ALCOHOL	000100516					
EPIDURAL; INJECTION		1				
IM - IV - SC; INJECTION		9		12/29/93	600	0.9% - 1.5%
IM - IV; INJECTION		93		06/30/94	600	0.001% - 15.0%
IM - IV; POWDER, FOR INJECTION SOLUTION		5		03/19/82	600	16.4MG - 66.9MG
IM - IV; SOLUTION, INJECTION		3		03/05/90	600	0.472% - 0.945%
IM - SC; INJECTION		15		07/25/83	600	0.9% - 2.2%
IM - SC; INJECTION, SUSTAINED ACTION		2		07/14/87	600	1.2%
INTERSTITIAL; INJECTION		1				
INTRA-ARTERIAL; INJECTION		1				
INTRA-ARTICULAR; INJECTION		24		04/09/86	600	0.001% - 1.0%
INTRABURSAL; INJECTION		5		02/13/74	600	0.9%
INTRACAVITARY; INJECTION		1				
INTRACAVITARY; POWDER, FOR INJECTION SOLUTION, LYOPHILI		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
BENZYL ALCOHOL	000100516					
INTRADERMAL; INJECTION		2		10/16/87	UNK	0.9%
INTRALESIONAL; INJECTION		8		10/16/87	UNK	0.9% - 1.0%
INTRAMUSCULAR; INJECTION		77		01/27/95	600	0.001% - 10.45%
INTRAMUSCULAR; POWDER, FOR INJECTION SOLUTION		2		02/27/85	UNK	
INTRAMUSCULAR; SOLUTION, INJECTION		1				
INTRAPERITONEAL; INJECTION		1				
INTRAPLEURAL; INJECTION		1				
INTRASYNOVIAL; INJECTION		11		02/17/84	600	0.9%
INTRATHECAL; INJECTION		2		05/09/86	600	0.45% - 0.9%
INTRATUMOR; INJECTION		2		05/09/86	600	0.45% - 0.9%
INTRAVENOUS; INJECTION		60		07/17/95	600	0.001% - 3.0%
INTRAVENOUS; POWDER, FOR INJECTION SOLUTION		1				
INTRAVENOUS; SOLUTION, INJECTION		4		12/15/95	UNK	0.9% - 2.02%
IV - SC; INJECTION		17		10/10/95	600	0.9% - 1.5%
IV(INFUSION); INJECTION		57		08/30/95	600	0.75% - 3.0%
IV(INFUSION); POWDER, FOR INJECTION SOLUTION		5		07/30/93	600	
IV(INFUSION); SOLUTION, INJECTION		1				
NERVE BLOCK; INJECTION		1				
ORAL; CAPSULE		36		12/20/95	520	
ORAL; CAPSULE, SOFT GELATIN		1				
ORAL; CAPSULE, SUSTAINED ACTION		9		08/02/88	UNK	1.231MG
ORAL; CONCENTRATE		1				
ORAL; SOLUTION		1				
ORAL; SUSPENSION		1				
ORAL; TABLET		3		01/05/89	110	0.49MG - 1.06MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		2		06/19/95	520	0.96MG - 2.31MG
ORAL; TABLET, SUSTAINED ACTION		1				
SOFT TISSUE; INJECTION		4		05/24/82	600	0.001% - 0.9%
SUBCONJUNCTIVAL; INJECTION		1				
SUBCUTANEOUS; INJECTION		4		02/18/86	600	0.9%
SUBCUTANEOUS; POWDER, FOR INJECTION SOLUTION		1				
TOPICAL; EMULSION, CREAM		30		09/20/95	UNK	0.2% - 2.2%
TOPICAL; LOTION		9		12/07/92	UNK	0.7% - 1.0%
TOPICAL; OINTMENT		3		10/09/85	600	
TOPICAL; SOLUTION		1				
TOPICAL; SUPPOSITORY		1				
URETERAL; SOLUTION		1				
VAGINAL; EMULSION, CREAM		6		12/04/95	600	1.0%
VAGINAL; SUPPOSITORY		1				
BENZYL BENZOATE	000120514					
INTRAMUSCULAR; INJECTION		8		07/30/81	600	0.01% - 46.0%
BENZYL CHLORIDE	000100447					
INTRAVENOUS; INJECTION		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
BETA-NAPHTHOL	000135193					
ORAL; CAPSULE		2		01/13/76	600	
BORIC ACID	010043353					
INTRAVENOUS; SOLUTION, INJECTION		1				
OPHTHALMIC; POWDER, FOR RECONSTITUTION		3		04/02/63	UNK	
OPHTHALMIC; SOLUTION		35		12/29/95	600	0.05% - 2.0%
OPHTHALMIC; SUSPENSION		3		12/28/82	600	0.6% - 1.0%
OTIC; SOLUTION		2		02/25/94	600	
TOPICAL; SHAMPOO		1				
BUFFER, ACETIC ACID-SODIUM ACETATE						
IM - IV - SC; INJECTION		1				
INTRA-ARTICULAR; INJECTION		1				
INTRAMUSCULAR; INJECTION		2		11/26/82	600	
INTRASYNOVIAL; INJECTION		1				
IV(INFUSION); INJECTION		1				
BUFFER, CITRIC ACID-SODIUM CITRATE						
IM - IV; INJECTION		1				
IV(INFUSION); INJECTION		1				
SUBCUTANEOUS; SOLUTION, INJECTION		1				
BUTANE	000106978					
TOPICAL; AEROSOL SPRAY		1				
TOPICAL; EMULSION, AEROSOL FOAM		1				
BUTYL ALCOHOL, TERTIARY	000075650					
TOPICAL; GEL		1				
BUTYLATED HYDROXYANISOLE	008003245					
INTRAMUSCULAR; INJECTION		1				
IV(INFUSION); INJECTION		2		08/08/85	510	0.0003%
NASAL; SPRAY, METERED		1				
ORAL; CAPSULE		1				
ORAL; CAPSULE, SOFT GELATIN		2		11/22/95	150	0.1MG - 0.2MG
ORAL; CONCENTRATE		1				
ORAL; GRANULE, FOR RECONSTITUTION		1				
ORAL; TABLET		3		10/31/91	600	0.04MG - 0.5MG
ORAL; TABLET, FILM COATED		1				
RECTAL; SUPPOSITORY		4		08/31/92	600	0.1025MG - 0.213MG
SUBLINGUAL; TABLET		2		04/16/81	600	0.5MG
TOPICAL; EMULSION, CREAM		2		12/23/82	UNK	0.0052%
TOPICAL; OINTMENT		4		09/30/83	UNK	0.005% - 0.02%
TOPICAL; SUPPOSITORY		2		04/26/93	520	
VAGINAL; EMULSION, CREAM		6		01/04/95	600	0.0012% - 0.0044%
VAGINAL; OINTMENT		1				
VAGINAL; SUPPOSITORY		2		04/26/93	520	1.0MG
BUTYLATED HYDROXYTOLUENE	000128370					
INHALATION; LIQUID		1				
INTRAMUSCULAR; INJECTION		1				
IV(INFUSION); INJECTION		2		08/08/85	510	0.001%
NASAL; SPRAY, METERED		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
BUTYLATED HYDROXYTOLUENE	000128370					
ORAL; CAPSULE		2		08/17/78	510	0.016MG - 0.2MG
ORAL; CAPSULE, SOFT GELATIN		1				
ORAL; TABLET		5		12/11/87	600	0.1MG - 0.4MG
ORAL; TABLET, SUSTAINED ACTION		1				
RECTAL; SUPPOSITORY		4		08/31/92	600	0.0125MG - 0.213MG
TOPICAL; EMULSION, AEROSOL FOAM		1				
TOPICAL; EMULSION, CREAM		7		11/20/92	UNK	0.02% - 0.1%
TOPICAL; GEL		2		10/05/78	UNK	0.05%
TOPICAL; OINTMENT		2		06/15/77	UNK	0.02%
TOPICAL; SOLUTION		2		05/04/77	UNK	0.05%
VAGINAL; EMULSION, CREAM		1				
VAGINAL; SUPPOSITORY		1				
BUTYLENE GLYCOL	000107880					
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
BUTYLPARABEN	000094268					
INTRAMUSCULAR; INJECTION		1				
ORAL; CAPSULE		28		12/20/95	520	
ORAL; CAPSULE, SUSTAINED ACTION		4		02/14/94	600	
ORAL; DROPS		1				
ORAL; SOLUTION		1				
ORAL; SUSPENSION		4		09/23/74	520	0.0058%
ORAL; SYRUP		1				
ORAL; TABLET		1				
ORAL; TABLET, COATED		3		09/17/69	120	0.0028MG - 0.004MG
ORAL; TABLET, REPEAT ACTION		2		03/31/81	UNK	0.006MG
ORAL; TABLET, SUSTAINED ACTION		5		11/14/94	UNK	0.04MG
RECTAL; SOLUTION		1				
TOPICAL; EMULSION, CREAM		6		04/29/94	600	0.2% - 0.4%
TOPICAL; LOTION		3		12/17/81	600	0.02%
TOPICAL; OINTMENT		3		12/23/83	600	0.18% - 0.3%
CAFFEINE	000058082					
OPHTHALMIC; SOLUTION		1				
CALCIUM	007440702					
IM - IV; INJECTION		1				
INTRAMUSCULAR; INJECTION		1				
CALCIUM ACETATE	000062544					
ORAL-21; TABLET		3		04/12/88	600	8.0MG - 8.3MG
ORAL-28; TABLET		5		02/09/89	600	8.3MG - 10.0MG
TOPICAL; EMULSION, CREAM		3		09/28/92	600	
CALCIUM ASCORBATE	005743271					
ORAL; SUSPENSION		1				
CALCIUM CARBONATE, PRECIPITATED	000471341					
ORAL; CAPSULE		2		12/31/93	510	125.68MG - 224.7MG
ORAL; CAPSULE, HARD GELATIN		1				
ORAL; CAPSULE, SUSTAINED ACTION		1				
ORAL; TABLET		32		04/16/91	600	4.17MG - 60.0MG

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
CALCIUM CARBONATE, PRECIPITATED	000471341					
ORAL; TABLET, COATED		18		02/25/92	600	0.72MG - 64.8MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
ORAL; TABLET, FILM COATED		1				
ORAL; TABLET, SUSTAINED ACTION		3		08/19/91	UNK	87.5MG - 229.7MG
ORAL-21; TABLET		1				
ORAL-28; TABLET		1				
OTIC; SOLUTION		2		02/25/94	600	0.382%
CALCIUM CHLORIDE	010035048					
CAUDAL BLOCK; INJECTION		1				
EPIDURAL; INJECTION		3		12/01/86	600	0.033%
IM - IV; INJECTION		5		05/02/88	600	0.004%
INTRAMUSCULAR; INJECTION		1				
INTRAOCULAR; SOLUTION		2		04/28/95	600	0.048%
INTRAPERITONEAL; SOLUTION		1				
NERVE BLOCK; INJECTION		6		12/01/86	600	0.024% - 0.033%
OPHTHALMIC; POWDER, FOR RECONSTITUTION		2		09/22/93	UNK	
ORAL; CONCENTRATE		2		04/27/83	600	0.008%
ORAL; SUSPENSION		1				
SUBCUTANEOUS; INJECTION		1				
CALCIUM GLUCEPTATE	017140602					
INTRAVENOUS; INJECTION		1				
CALCIUM HYDROXIDE	001305620					
ORAL; SUSPENSION		1				
TOPICAL; EMULSION, CREAM		1				
CALCIUM LACTATE	000814802					
VAGINAL; TABLET		1				
CALCIUM PHOSPHATE	010103465					
ORAL; CAPSULE		1				
ORAL; TABLET		23		11/18/93	110	21.5MG - 160.0MG
ORAL; TABLET, COATED		3		01/15/70	510	
ORAL; TABLET, FILM COATED		4		03/15/78	120	51.5MG - 362.0MG
ORAL; TABLET, REPEAT ACTION		1				
ORAL-21; TABLET		2		12/30/81	510	82.9MG - 86.0MG
ORAL-28; TABLET		2		12/30/81	510	86.0MG
CALCIUM PHOSPHATE DIBASIC DIHYDRATE-SUCROSE AGGLOMERATE						
ORAL; TABLET		1				
CALCIUM PHOSPHATE, DIBASIC	007757939					
ORAL; CAPSULE		2		04/10/84	600	1.8MG - 2.4MG
ORAL; CAPSULE, SUSTAINED ACTION		2		04/18/62	120	5.0MG - 234.04MG
ORAL; PASTILLE		1				
ORAL; SYRUP		1				
ORAL; TABLET		224		11/30/95	600	0.031MG - 850.0MG
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		1				
ORAL; TABLET, COATED		10		12/20/82	600	35.0MG - 168.0MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
ORAL; TABLET, DISPERSIBLE		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
CALCIUM PHOSPHATE, DIBASIC	007757939					
ORAL; TABLET, FILM COATED		4		12/12/95	120	101.48MG - 136.25MG
ORAL; TABLET, SUSTAINED ACTION		2		08/21/92	UNK	
ORAL-21; TABLET		2		04/12/88	600	40.531MG
ORAL-28; TABLET		4		02/09/89	600	40.531MG - 104.5MG
TOPICAL; SHAMPOO		1				
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE	007789777					
ORAL; CAPSULE		1				
ORAL; TABLET		39		09/29/95	600	5.55MG - 378.78MG
ORAL; TABLET, COATED		3		10/03/77	600	73.3MG - 219.9MG
ORAL; TABLET, FILM COATED		3		12/29/92	120	26.7MG - 366.3MG
ORAL; TABLET, SUSTAINED ACTION		1				
CALCIUM PHOSPHATE, TRIBASIC	012167747					
ORAL; CAPSULE, SUSTAINED ACTION		1				
ORAL; TABLET		9		11/24/93	UNK	9.26MG - 284.0MG
ORAL; TABLET, COATED		6		01/26/84	510	14.0MG - 21.0MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
ORAL; TABLET, SUSTAINED ACTION		3		07/13/87	UNK	100.0MG
ORAL-28; TABLET		1				
CALCIUM PYROPHOSPHATE	007790763					
ORAL; TABLET		4		03/22/78	600	128.52MG - 298.04MG
CALCIUM SILICATE	010101390					
ORAL; TABLET		1				
ORAL; TABLET, COATED		1				
ORAL; TABLET, SUSTAINED ACTION		5		03/23/87	600	4.0MG - 15.0MG
CALCIUM STEARATE	001592230					
ORAL; CAPSULE		16		12/26/90	150	0.114MG - 21.1MG
ORAL; CAPSULE, SUSTAINED ACTION		17		03/16/89	600	7.93MG - 91.9MG
ORAL; TABLET		83		09/29/95	600	0.23MG - 21.0MG
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		4		06/28/89	600	15.0MG - 47.5MG
ORAL; TABLET, FILM COATED		6		04/28/95	600	4.6MG - 10.0MG
ORAL; TABLET, SUSTAINED ACTION		5		10/22/85	600	10.0MG - 20.0MG
SUBLINGUAL; TABLET		2		02/23/78	600	2.0MG
CALCIUM SULFATE	007778189					
ORAL; CAPSULE		3		10/15/84	180	50.0MG - 74.68MG
ORAL; CAPSULE, SUSTAINED ACTION		2		08/02/76	120	0.53MG - 1.54MG
ORAL; SYRUP		1				
ORAL; TABLET		30		02/15/89	600	0.038MG - 307.6MG
ORAL; TABLET, COATED		11		08/16/85	120	4.532MG - 170.0MG
ORAL; TABLET, FILM COATED		2		12/30/83	110	221.0MG - 443.0MG
ORAL; TABLET, REPEAT ACTION		2		03/31/81	UNK	235.0MG
ORAL; TABLET, SUSTAINED ACTION		8		11/14/94	UNK	340.0MG
ORAL-28; TABLET		3		11/17/95	510	10.7MG
CALCIUM SULFATE DIHYDRATE	010101414					
ORAL; CAPSULE		2		11/21/74	160	2.6MG - 370.0MG
ORAL; TABLET		8		05/24/82	600	17.45MG - 279.309MG
ORAL; TABLET, COATED		10		01/04/82	600	12.36MG - 214.24MG

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
CALCIUM SULFATE DIHYDRATE	010101414					
ORAL; TABLET, SUSTAINED ACTION		1		--		
CALCIUM SULFATE, ANHYDROUS						
ORAL; TABLET		1				
ORAL; TABLET, COATED		2		01/26/84	510	
ORAL-28; TABLET		1				
CALDIAMIDE SODIUM	122760912					
INTRAVENOUS; SOLUTION, INJECTION		1				
CALTERIDOL CALCIUM	121915831					
INTRAVENOUS; INJECTION		1				
CANDELILLA WAX						
ORAL; TABLET		6		11/19/91	110	0.05MG - 0.316MG
ORAL; TABLET, FILM COATED		1				
ORAL; TABLET, SUSTAINED ACTION		2		05/24/83	600	
CANOLA OIL	008002139					
ORAL; CAPSULE, SOFT GELATIN		1				
CAPRYLIC/CAPRIC DIGLYCERYL SUCCINATE						
ORAL; AEROSOL		1				
CAPRYLIC/CAPRIC TRIGLYCERIDE						
ORAL; CAPSULE, SOFT GELATIN		1				
TOPICAL; AEROSOL SPRAY		1				
TOPICAL; EMULSION, CREAM		1				
TOPICAL; SOLUTION		1				
CARAMEL	008028895					
ORAL; CAPSULE		1				
ORAL; GRANULE		1				
ORAL; POWDER, FOR RECONSTITUTION		1				
ORAL; SOLUTION		3		12/03/86	600	
ORAL; SYRUP		4		03/02/87	600	
RECTAL; POWDER, FOR RECONSTITUTION		1				
TOPICAL; EMULSION, CREAM		1				
CARBOMER						
ORAL; TABLET, SUSTAINED ACTION		2		08/12/81	600	96.0MG
CARBOMER 1342	009003014					
TRANSDERMAL; FILM, CONTROLLED RELEASE		1				
CARBOMER 934	009007163					
ORAL; SUSPENSION		2		08/29/78	120	
RECTAL; ENEMA		2		05/27/94	600	
TOPICAL; EMULSION, CREAM		4		06/06/84	600	0.9%
TOPICAL; GEL		1				
TOPICAL; LOTION		12		09/30/94	600	0.25% - 0.4%
TOPICAL; OINTMENT		1				
TOPICAL; SOLUTION		2		12/15/95	600	0.15%
CARBOMER 934P						
OPHTHALMIC; SUSPENSION		2		12/30/94	UNK	0.2%
ORAL; CAPSULE		1				
ORAL; TABLET, SUSTAINED ACTION		1				

INACTIVE INGREDIENTS FOR CURRENTLY MARKETED DRUG PRODUCTS

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
CARBOMER 934P						
TOPICAL; EMULSION, CREAM		2		12/30/92	UNK	0.1% - 1.0%
TOPICAL; GEL		3		04/29/94	UNK	0.9% - 1.5%
TOPICAL; LOTION		4		01/31/90	600	0.3%
TOPICAL; OINTMENT		1				
TOPICAL; SOLUTION		1				
VAGINAL; GEL		1				
CARBOMER 940	009007174					
OPHTHALMIC; GEL		1				
TOPICAL; CREAM, AUGMENTED		1				
TOPICAL; EMULSION, CREAM		4		06/13/88	600	0.1% - 0.5%
TOPICAL; GEL		7		12/30/94	600	0.6% - 3.5%
TOPICAL; LOTION		3		11/26/85	600	0.203% - 0.6%
CARBOMER 941	009003014					
TOPICAL; LOTION		2		12/07/92	UNK	0.05% - 0.1%
CARBOMER 974	009003014					
ORAL; GRANULE, FOR RECONSTITUTION		1				
CARBON DIOXIDE	000124389					
INHALATION; GAS		1				
INTRA-ARTERIAL; SOLUTION, INJECTION		1				
INTRACARDIAC; INJECTION		1				
INTRAMUSCULAR; INJECTION		1				
INTRATHECAL; INJECTABLE		1				
INTRATHECAL; INJECTION		1				
INTRAVASCULAR; SOLUTION, INJECTION		1				
INTRAVENOUS; INJECTION		2		08/23/78	160	
INTRAVENOUS; SOLUTION, INJECTION		1				
IV(INFUSION); POWDER, FOR INJECTION SOLUTION		1				
NERVE BLOCK; INJECTION		4		06/21/88	600	
CARBOXY VINYL COPOLYMER						
TOPICAL; GEL		1				
CARBOXYMETHYL STARCH	009057061					
ORAL; TABLET		6		03/25/91	600	4.75MG - 16.0MG
CARBOXYMETHYLAMYLOPECTIN SODIUM						
ORAL; TABLET		1				
CARBOXYMETHYLCELLULOSE	009000117					
INTRA-ARTICULAR; INJECTION		1				
INTRAMUSCULAR; INJECTION		4		05/24/79	520	0.1% - 0.9%
ORAL; CAPSULE, SUSTAINED ACTION		2		04/23/85	UNK	
ORAL; DROPS		1				
ORAL; POWDER, FOR RECONSTITUTION		2		12/31/91	520	
ORAL; SUSPENSION		3		11/17/86	600	
ORAL; TABLET		4		02/27/84	600	2.0MG - 10.8MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
RECTAL; SUSPENSION		1				

INGREDIENT ROUTE/DOSAGE FORM	CAS #	NDA COUNT	LAST NDA	APPROVAL DATE	DIV	POTENCY RANGE
CARBOXYMETHYLCELLULOSE CALCIUM	009050048					
ORAL; TABLET		2		02/21/92	520	4.0MG - 80.0MG
ORAL; TABLET, DELAYED ACTION, ENTERIC COATED		1				
ORAL; TABLET, FILM COATED		1				
CARBOXYMETHYLCELLULOSE SODIUM	009004324					
DENTAL; GEL		1				
DENTAL; PASTE		4		07/06/87	600	0.3% - 16.7%
INTRA-ARTICULAR; INJECTION		13		05/24/82	600	0.1% - 0.75%
INTRABURSAL; INJECTION		5		02/13/74	600	0.1% - 0.75%
INTRADERMAL; INJECTION		2		10/16/87	UNK	0.75%
INTRALESIONAL; INJECTION		3		10/16/87	UNK	0.5% - 0.75%
INTRAMUSCULAR; INJECTION		18		07/07/83	600	0.1% - 0.75%
INTRASYNOVIAL; INJECTION		5		11/05/81	600	0.1% - 0.75%
NASAL; SPRAY, METERED		3		10/19/94	UNK	1.5%
ORAL; CAPSULE		12		10/18/95	600	0.068MG - 160.0MG
ORAL; DROPS		1				
ORAL; GRANULE		5		06/15/88	600	
ORAL; GRANULE, FOR RECONSTITUTION		1				
ORAL; POWDER, FOR RECONSTITUTION		17		04/28/95	600	0.066% - 0.525%
ORAL; SOLUTION		6		07/10/95	600	0.2% - 3.5%
ORAL; SUSPENSION		26		09/15/95	180	0.13% - 1.2%
ORAL; SYRUP		10		02/03/86	600	0.265% - 2.65%
ORAL; TABLET		14		05/31/94	530	0.57MG - 41.8MG
ORAL; TABLET (IMMED./COMP. RELEASE), UNCOATED,		2		07/05/88	520	24.75MG
ORAL; TABLET, COATED		4		05/19/81	600	2.2MG
SOFT TISSUE; INJECTION		2		05/24/82	600	0.1% - 0.5%
SUBCUTANEOUS; INJECTION		1				
TOPICAL; GEL, JELLY		1				
TOPICAL; PASTE		1				
TOPICAL; SOLUTION		1				
CARBOXYPOLYMETHYLENE	009007209					
ORAL; SUSPENSION		1				
RECTAL; ENEMA		1				
TOPICAL; LOTION		1				
CARDAMOM						
ORAL; SOLUTION, ELIXIR		1				
CARMINE	008022933					
ORAL; TABLET		1				
ORAL; TABLET, UNCOATED, TROCHE		1				
CARMINE SOLUTION	008001807					
ORAL; SUSPENSION		1				
ORAL; SYRUP		1				
CARMINIC ACID	000476391					
ORAL; TABLET		1				