

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DDLRC-RX Drug Study Bulletin # 300

DATE: APR 15 1993

FROM: Chief  
Prescription Drug Compliance Branch (HFD-313)  
Division of Drug Labeling Compliance

SUBJECT: Removal of Organidin and Other Iodinated Glycerol  
Containing Prescription Drug Products Sold as  
Mucolytic-Expectorants from the Market.

TO: All Regional Food and Drug Directors  
All District Directors  
Attn: DESI Coordinators  
Compliance Branch Chiefs

PURPOSE:

To advise the Districts of a regulatory class action being implemented against prescription drug products that contain iodinated glycerol as an ingredient. These products are on the market as mucolytic-expectorants with labeling for a variety of respiratory tract conditions, without FDA approval. Because of safety concerns, we are prepared to take enforcement action against these products as unapproved new drugs.

BACKGROUND:

Organidin or iodinated glycerol consists of a mixture of several iodinated compounds formed by reaction of iodine and glycerine. This drug has been marketed as a mucolytic-expectorant for over 50 years. The drug is labeled for use in treating a wide variety of respiratory tract conditions, including bronchitis, pulmonary tract conditions, cystic fibrosis, chronic sinusitis and prevention of post-operative atelectasis.

Because iodinated glycerol has been marketed without approved NDA, the drug was not included in the DESI review. Enforcement action under the new drug provisions of the Act has been deferred under the terms of CPG 7132c.02, Marketed New Drugs Without FDA Approval. Under the policy guide such drugs would not be subject to regulatory action under the priorities stated unless new information developed that would question the safety or effectiveness of the drug.

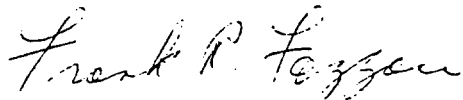
FDA now has information about the carcinogenic potential of iodinated glycerol. FDA recently reviewed the National Toxicology Program (NTP) Technical Report of the Toxicity and Carcinogenesis Studies of Iodinated Glycerol (Organidin), No. 340 that was published in March of 1990. The study indicated that there was some evidence of carcinogenic activity for male F344/N rats and female B6C3F1 mice administered iodinated glycerol in 2-year gavage studies. Based on the safety issues described in the NTP report, the scant evidence of benefit from using the drug, and the availability of alternative therapies, the agency concurred with this report and determined that the benefit does not justify the risk associated with use of the drug.

In view of the above, FDA is initiating regulatory action (as a new drug) against iodinated glycerol containing products, as outlined under Exemption No. 2 of CPG 7132c.02. Using established DESI procedures, we are issuing Warning Letters for those products specifically identified in this Drug Study Bulletin to firms in your respective Districts. Copies of Warning Letters issued to firms in your district are attached.

Prescription Drug Compliance Branch (HFD-313) will monitor the replies from firms involved and furnish copies to the appropriate district. We will also issue assignments where further follow-up is indicated.

A list of all firms with their products receiving Warning Letters is attached. If your District is aware of any additional products which may be subject to this announcement, please contact the National Coordinator so that additional Warning Letters may be issued.

National Coordinator: Emily Florio (HFD-313) 301/295-8073.



Frank R. Fazzari

#### Attachments

Copies of Warning Letters  
List of firms and products

**PRESCRIPTION DRUGS MARKETED WITHOUT APPROVAL  
CONTAINING IODINATED GLYCEROL  
DDLC-RX DRUG STUDY BULLETIN #300**

FIRM	DISTR	TYPE	PRODUCT	INGREDIENTS
MY-K Labs Inc. Unknown OUT OF BUSINESS		M	Myodine DM Liquid	10 mg - Dextromethorphan Hydrobromide 30 mg - Glycerol, Iodinated
Cheshire Drugs 2280 Cheshire Bridge Road Atlanta, GA 30324	HFR-SE1 HFR-SE100 HFR-SE140	R	Iophen-C Liquid Iophen-DM	30 mg - Glycerol, Iodinated 10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated
Cheshire Drugs 2280 Cheshire Bridge Road Atlanta, GA 30324	HFR-SE1 HFR-SE100 HFR-SE140	R		30 mg - Glycerol, Iodinated 15 mg - Iodine 10 mg - Dextromethorphan Hydrobromide
Denco (Qualitest) 1025 Jordan Rd Huntsville, AL 35811	HFR-SE1 HFR-SE100 HFR-SE140	L	Iophen C Liquid	30 mg - Iodinated Glycerol 10 mg - Codeine Phosphate
Qualitest Products, Inc. 1025 Jordan Rd. Huntsville, AL 35811	HFR-SE1 HFR-SE100 HFR-SE140	L	Iophen-C Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated

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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Qualitest 1025 Jordan Rd. Huntsville, AL 35811	HFR-SE1 HFR-SE300 HFR-SE330	L	Iophen Solution 50 MG/ML	50 mg - Glycerol, Iodinated
Scrippak, Inc. 11940 Alpharetta Hwy. STE 130 Alpharetta, GA 30201	HFR-SE1 HFR-SE100 HFR-SE140	L R	Iophen C Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated
Barre-National, Inc. 7205 Windsor Blvd. Baltimore, MD 21207	HFR-MA1 HFR-MA200 HFR-MA240	M	Iophen DM Liquid	30 mg - Iodinated Glycerol 10 mg - Dextromethorphan Hydrobromide 15 mg - Iodine
Barre-National, Inc. 7205 Windsor Blvd. Baltimore, MD 21207	HFR-MA1 HFR-MA200 HFR-MA240	M	Iophen Elixir	60 mg - Iodinated Glycerol 30 mg - Iodine
Barre-National, Inc. 7205 Windsor Blvd. Baltimore, MD 21207	HFR-MA1 HFR-MA200 HFR-MA240	M	Iophylline Elixir	120 mg - Theophylline 30 mg - Iodinated Glycerol 15 mg - Iodine
Barre-National, Inc. 7205 Windsor Blvd. Baltimore, MD 21207	HFR-MA1 HFR-MA200 HFR-MA240	R	Iophen Solution	50 mg - Iodinated Glycerol 25 mg - Iodine
Barre-National, Inc. 7205 Windsor Blvd. Baltimore, MD 21207	HFR-MA1 HFR-MA200 HFR-MA240	M	Iophen-C Liquid	10 mg - Codeine Phosphate 30 mg - Iodinated Glycerol 15 mg - Iodine

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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Schein Pharmaceutical, Inc. 131 West Street Danbury, CT 06810	HFR-NE1 HFR-NE200 HFR-NE240	L	Iophen-C Liquid	
Schein Pharmaceutical, Inc. 131 West Street Danbury, CT 06810	HFR-NE1 HFR-NE200 HFR-NE240		Iophen DM Liquid	
Schein Pharmaceutical, Inc. 131 West Street Danbury, CT 06810	HFR-NE1 HFR-NE200 HFR-NE240		Iodinated Glycerol Tablets 30 MG	
Turrill Drug Incorporated 800 Federal Road Brookfield, CT 06804	HFR-NE1 HFR-NE200 HFR-NE240	R	Iophen DM Syrup	
DRX Pharmaceutical Consultants, Inc. 8135 N. Monticello Ave. Skokie, IL 60076	HFR-MW1 HFR-MW100 HFR-MW140	R	Iophen C Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated
DRX Pharmaceutical Consultants, Inc. 8135 N. Monticello Ave. Skokie, IL 60076	HFR-MW1 HFR-MW100 HFR-MW140	R	Iodinated Glycerol With DM	

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FIRM	DIBT	TYPE	PRODUCT	INGREDIENTS
Pharmaceutical Basics, Inc. 6451 West Main Street Morton Grove, IL 60053	HFR-MW1 HFR-MW100 HFR-MW140	M	Iodinated Glycerol and Codeine Phosphate Liquid	30 mg - Glycerol, Iodinated 10 ns - Codeine Phosphate
Pharmaceutical Basics, Inc. 6451 West Main Street Morton Grove, IL 60053	HFR-MW1 HFR-MW100 HFR-MW140	M	Iodinated Glycerol Elixir 60 MG/5ML	60 mg - Glycerol, Iodinated
Pharmaceutical Basics, Inc. 6451 West Main Street Morton Grove, IL 60053	HFR-MW1 HFR-MW100 HFR-MW140	M	Iodinated Glycerol DM Liquid	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide
Unit Dose Laboratories, Inc. 1718 Northrock Court Rockford, IL 61103	HFR-MW1 HFR-MW100 HFR-MW140	R	Iodinated Glycerol and Dextromethorphan Hydrobromide	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide 15 mg - Iodine
Unit Dose Laboratories, Inc. 1718 Northrock Court Rockford, IL 61103	HFR-MW1 HFR-MW100 HFR-MW140	R	Iodinated Glycerol Liquid with Codeine Phosphate	10 mg - Codeine Phosphate 15 mg - Iodine 30 mg - Glycerol, Iodinated
Unit Dose Laboratories, Inc. 1718 Northrock Court Rockford, IL 61103	HFR-MW1 HFR-MW100 HFR-MW140	R	Iodinated Glycerol Elixir	60 mg - Glycerol, Iodinated 30 mg - Iodine

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DDL-C-RX DRUG STUDY BULLETIN #300

FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Physicians Total Care, Inc. 105 East Main Stigler, OK 74462	HFR-SW1 HFR-SW100 HFR-SW140	R N	Iophen-C Liquid	30 mg - Glycerol, Iodinated 10 mg - Codeine Phosphate 15 mg - Iodine
Physicians Total Care, Inc. 105 East Main Stigler, OK 74462	HFR-SW1 HFR-SW100 HFR-SW140	R N	Tussi-Organidin Liquid	30 mg - Glycerol, Iodinated 10 mg - Codeine Phosphate 15 mg - Iodine
Geneva Pharmaceuticals, Inc. 2599 West Midway Blvd. Broomfield, CO 80020	HFR-SW1 HFR-SW200 HFR-SW240	L	Iodinated Glycerol DM Liquid	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide
Geneva Pharmaceuticals, Inc. 2599 West Midway Blvd. Broomfield, CO 80020	HFR-SW1 HFR-SW200 HFR-SW240	L	Iodinated Glycerol Tablets 30 mg	30 mg - Glycerol, Iodinated
Geneva Pharmaceuticals, Inc. 2599 West Midway Blvd. Broomfield, CO 80020	HFR-SW1 HFR-SW200 HFR-SW240	L	Iodinated Glycerol/Codeine	30 mg - Glycerol, Iodinated 10 ns - Codeine Phosphate
Geneva Pharmaceuticals, Inc. 2599 West Midway Blvd. Broomfield, CO 80020	HFR-SW1 HFR-SW200 HFR-SW240	L	Iodinated Glycerol Elixir	60 mg - Glycerol, Iodinated

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FIRM	DISTR	TYPE	PRODUCT	INGREDIENTS
Veratex Corporation 1304 E. Maple Troy, MI 48084	HFR-MW1 HFR-MW200 HFR-MW240	L	Tussi Organidin Liquid	30 mg - Glycerol, Iodinated 10 mg - Codeine Phosphate
Med-Pro, Inc. 210 East 4th St., Box 694 Lexington, NE 68850	HFR-SW1 HFR-SW300 HFR-SW340	R	Iophen-C-Liquid	
Med-Pro, Inc. 210 East 4th St. Box 694 Lexington, NE 68850	HFR-SW1 HFR-SW300 HFR-SW340	R	Organidin solution	50 mg - Glycerol, Iodinated 25 mg - Iodine
Med-Pro, Inc. 210 East 4th St. Box 694 Lexington, NE 68850	HFR-SW1 HFR-SW300 HFR-SW340	R	Iodinated glycerol 30 MG/ Dextromethorphan HBR 10 M Dose: Liquid	10 mg - Dextromethorphan Hydrobromide 30 mg - Glycerol, Iodinated 15 mg - Iodine
Med-Pro, Inc. 210 East 4th St. Box 694 Lexington, NE 68850	HFR-SW1 HFR-SW300 HFR-SW340	R	Iodinated Glycerol 60 MG/5 ML Elixir	60 mg - Glycerol, Iodinated 30 mg - Iodine
Med-Pro 210 East 4th St. Box 694 Lexington, NE 68850	HFR-SW1 HFR-SW300 HFR-SW340	R	Iodinated Glycerol 30 MG/Codeine Phosphate 10 MG Per dose: Syrup	30 mg - Glycerol, Iodinated 10 mg - Codeine Phosphate



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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Anabolic, Inc. 17802 Gillette Ave. Irvine, CA 92714	HFR-P1 HFR-P200 HFR-P240	M	Iodrol Tablets	30 mg - Iodinated Glycerol 15 mg - Iodine
Clinical Pharm 861 Nancy Ridge Rd. San Diego, CA 92121	HFR-P1 HFR-P200 HFR-P240	N M R	Organidin 30 mg Tabs	30 mg - Iodinated Glycerol
Clinical Pharm 861 Nancy Ridge Rd. San Diego, CA 92121	HFR-P1 HFR-P200 HFR-P240	N M R	Iophen DM Syrup	30 mg - Iodinated Glycerol 10 mg - Dextromethorphan Hydrobromide
Clinical Pharm 861 Nancy Ridge Rd. San Diego, CA 92121	HFR-P1 HFR-P200 HFR-P240	N M R	Iophen-C Syrup	30 mg - Iodinated Glycerol 10 mg - Codeine Phosphate
Clinical Pharm 861 Nancy Ridge Rd. San Diego, CA 92121	HFR-P1 HFR-P200 HFR-P240	N M R	Iophen Elixir 60mg/5ml	60 mg - Iodinated Glycerol
Compumed Inc. 1517 Edwards Ave. Harahan, LA 70123	HFR-SE1 HFR-SE400 HFR-SE440	R	Organidin 30 mg Tablets	30 mg - Iodinated Glycerol
Compumed Inc. 1517 Edwards Ave. Harahan, LA 70123	HFR-SE1 HFR-SE400 HFR-SE440	N R	Iodinated Glycerol Elixir 60 mg/5ml	60 mg - Iodinated Glycerol

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DDLC-RX DRUG STUDY BULLETIN #300

FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Omega Laboratories 1125 North Corporate Drive Mobile, AL 36607	HFR-SE1 HFR-SE300 HFR-SE330	R	Tussi-Organidin DM Solution	15 mg - Glycerol, Iodinated 30 mg - Iodine 10 mg - Dextromethorphan Hydrobromide
Omega Laboratories 1125 North Corporate Drive Mobile, AL 36607	HFR-SE1 HFR-SE300 HFR-SE330	R	Oridol-DM Liquid	10 mg - Dextromethorphan Hydrobromide 30 mg - Glycerol, Iodinated
Omega Laboratories 1125 North Corporate Drive Mobile, AL 36607	HFR-SE1 HFR-SE300 HFR-SE330	R	Iophen DM syrup	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide
Omega Laboratories 1125 North Corporate Drive Mobile, AL 36607	HFR-SE1 HFR-SE300 HFR-SE330	R	Iophen-C Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated
Omega Laboratories 1125 North Corporate Drive Mobile, AL 36607	HFR-SE1 HFR-SE300 HFR-SE330	R	Oridol-C 5 MG/5 ML Syrup	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated
Omega Laboratories 1125 North Corporate Drive Mobile, AL 36607	HFR-SE1 HFR-SE300 HFR-SE330	R	Tussi-Organidin DM Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated

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FIRM	DIBT	TYPE	PRODUCT	INGREDIENTS
Pharmpak, Inc. 186 Paterson Avenue East Rutherford, NJ 07073	HFR-MA1 HFR-MA300 HFR-MA330	NR	Tussi-Organidin DM Liquid	30 mg - Glycerol, Iodinated 15 mg - Iodine 10 mg - Dextromethorphan Hydrobromide
Wallace Laboratories, Division of Carter Wallace, Inc. Half Acre Road Cranbury, NJ 08512	HFR-MA1 HFR-MA300 HFR-MA330	L	Tuss Organidin	10 mg - Codeine Phosphate 15 mg - Iodine 30 mg - Glycerol, Iodinated
Wallace Laboratories, Division of Carter Wallace, Inc. Half Acre Road Cranbury, NJ 08512	HFR-MA1 HFR-MA300 HFR-MA330	L	Organidin	50 mg - Glycerol, Iodinated 25 mg - Iodine 60 mg - Glycerol, Iodinated 30 mg - Iodine 30 mg - Glycerol, Iodinated 15 mg - Iodine
Wallace Laboratories, Division of Carter Wallace, Inc. Half Acre Road Cranbury, NJ 08512	HFR-MA1 HFR-MA300 HFR-MA330	L	Theo Organidin	120 mg - Theophylline 30 mg - Glycerol, Iodinated 15 mg - Iodine

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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Rugby Lab 898 Orlando Ave. West Hempstead, NY 11552	HFR-NE1 HFR-NE100 HFR-NE140	L	Iophen Solution	50 mg - Glycerol, Iodinated 25 mg - Iodine
Rugby Lab 898 Orlando Ave. West Hempstead, NY 11552	HFR-NE1 HFR-NE100 HFR-NE140	L	Iophen Elixir	60 mg - Glycerol, Iodinated 30 mg - Iodine
Rugby Lab 898 Orlando Ave. West Hempstead, NY 11552	HFR-NE1 HFR-NE100 HFR-NE140	L	Iophen DM Elixir	10 mg - Dextromethorphan Hydrobromide 30 mg - Glycerol, Iodinated 15 mg - Iodine
Rugby Lab 898 Orlando Ave. West Hempstead, NY 11552	HFR-NE1 HFR-NE100 HFR-NE140	L	Iophen	30 mg - Glycerol, Iodinated 15 mg - Iodine
Rugby Lab 898 Orlando Ave. West Hempstead, NY 11552	HFR-NE1 HFR-NE100 HFR-NE140	L	Iophen-C Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated 15 mg - Iodine

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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Goldline Laboratories, Inc. 1900 W. Commercial Blvd. Ft. Lauderdale, FL 33309	HFR-SE1 HFR-SE200 HFR-SE240	L	Iophen	25 mg - Iodine 50 mg - Glycerol, Iodinated
Goldline Laboratories, Inc. 1900 W. Commercial Blvd. Ft. Lauderdale, FL 33309	HFR-SE1 HFR-SE200 HFR-SE240	L	Iodinated Glycerol, Iodinated	30 mg - Glycerol, Iodinated 15 mg - Iodine
Goldline Laboratories, Inc. 1900 W. Commercial Blvd. Ft. Lauderdale, FL 33309	HFR-SE1 HFR-SE200 HFR-SE240	L	Tuss-R-Gen DM	10 mg - Dextromethorphan Hydrobromide 30 mg - Glycerol, Iodinated 15 mg - Iodine
Goldline Laboratories, Inc. 1900 W. Commercial Blvd. Ft. Lauderdale, FL 33309	HFR-SE1 HFR-SE200 HFR-SE240	L	Theo-R-Gen	120 mg - Theophylline 30 mg - Glycerol, Iodinated 15 mg - Iodine

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FIRM	DISTR	TYPE	PRODUCT	INGREDIENTS
Kramer Pharmaceutical, Inc. 3307 NW 74th Avenue Miami, FL 33122	HFR-SE1 HFR-SE200 HFR-SE240	L	Tussi-Pres Antitussive- Mucolytic- Expectorant	
Mason Distributors, Inc. 5105 Northwest 159th St. Hialeah, FL 33014	HFR-SE1 HFR-SE200 HFR-SE240	L	Iodur Elixir 60 MG/5 ML	60 mg - Glycerol, Iodinated
Mason Distributors, Inc. 5105 Northwest 159th St. Hialeah, FL 33014	HFR-SE1 HFR-SE200 HFR-SE240	L	Iodur with Codeine Liquid	100 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated
Mason Distributors, Inc. 5105 Northwest 159th St. Hialeah, FL 33014	HFR-SE1 HFR-SE200 HFR-SE240	L	Iodur DM Liquid Antitussive	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide 15 mg - Iodine

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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Thrift Drug, Inc. 615 Alpha Drive Pittsburgh, PA 15238	HFR-MA1 HFR-MA100 HFR-MA140	R	Tussi-Organidin DM Liquid	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide
United Research Laboratories 3600 Meadow Lane Bensalem, PA 19020	HFR-MA1 HFR-MA100 HFR-MA140	L	Iophen Elixir	60 mg - Glycerol, Iodinated 30 mg - Iodine
United Research Laboratories 3600 Meadow Lane Bensalem, PA 19020	HFR-MA1 HFR-MA100 HFR-MA140	L	Iophen-C Liquid	10 mg - Codeine Phosphate 30 mg - Glycerol, Iodinated 15 mg - Iodine
United Research Laboratories 3600 Meadow Lane Bensalem, PA 19020	HFR-MA1 HFR-MA100 HFR-MA140	L	Iodinated Glycerol 30 MG Tablets	30 mg - Glycerol, Iodinated
United Research Laboratories 3600 Meadow Lane Bensalem, PA 19020	HFR-MA1 HFR-MA100 HFR-MA140	L	Iophen DM	10 mg - Dextromethorphan Hydrobromide 30 mg - Glycerol, Iodinated 15 mg - Iodine
HR Cenci Labs, Inc. 152 N. Broadway Fresno, CA 93701	HFR-P1 HFR-P100 HFR-P140	M	Iocen-DM Liquid	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide

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FIRM	DIST	TYPE	PRODUCT	INGREDIENTS
Pharmedix Co. 3519 Breakwater Ave. Hayward, CA 94545	HFR-P1 HFR-P100 HFR-P140	R N	Iophen Elixir	30 mg - Iodine 60 mg - Glycerol, Iodinated
Pharmedix Co. 3519 Breakwater Ave. Hayward, CA 94545	HFR-P1 HFR-P100 HFR-P140	R N	Iophen C	30 mg - Glycerol, Iodinated 10 mg - Codeine Phosphate
Pharmedix Co. 3519 Breakwater Ave. Hayward, CA 94545	HFR-P1 HFR-P100 HFR-P140	R N	Iophen DM	10 mg - Dextromethorphan Hydrobromide 30 - Glycerol, Iodinated
Tuality Forest Grove Hospital 1809 Maple Street Forest Grove, OR 97116	HFR-P1 HFR-P300 HFR-P330	R N H	Iophen 60 MG/ 5 ML Elixir	60 mg - Glycerol, Iodinated
Mercantile Plaza Pharmacy 3975 S W Mercantile Drive Lake Oswego, OR 97035	HFR-P1 HFR-P300 HFR-P330	R	Tussi Organidin DM Liquid	30 mg - Glycerol, Iodinated 10 mg - Dextromethorphan Hydrobromide
Bergmar Pharmaceutical De Diego 590 Rio Piedras, PR 00924	HFR-SE1 HFR-SE500 HFR-SE540	L	Tuss-Mine with Codeine Liquid	30 mg - Iodinated Glycerol 10 mg - Codeine Phosphate