DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Glen E. Tullman
Allscripts Healthcare Solutions
2401 Commerce Dr
Libertyville, IL 60048

Products: Guaifenesin Sustained Release Tablets 600 mg
Humibid LA Tablets 600 mg
Fenesin Tablets 600 mg
Duratuss G 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

Guaifenesin is a drug that presently has an established general recognition of safety and effectiveness under the OTC Monograph system as an expectorant (21 CFR 341), but the OTC monograph system does not include provisions for extended release dosage form drug products. The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations at section 310.502(a)(14), codifies the new drug status of extended release drug products. Therefore, single ingredient guaifenesin extended release drug products are new drugs and require an approved application for marketing.

Before there was a New Drug Application (NDA) approved for a single ingredient guaifenesin extended release product, FDA did not expend scarce enforcement resources to address such unapproved drugs. However, on July 12, 2002, FDA approved NDA 21-282 covering the marketing of Mucinex 600 mg, a guaifenesin extended release tablet expectorant for patients 12 years and above. Other single ingredient extended release guaifenesin drug products, which are new drugs, must be approved under an NDA or abbreviated new drug application (ANDA) as required by the Federal Food, Drug, and Cosmetic Act (the Act).

There are no approved applications under the provisions of Section 505 on file with the FDA for the previously listed products marketed by your firm. Therefore, the marketing of these products without an approved new drug application constitutes a violation of Section 505(a) of the Act.

We request that you reply within fifteen (15) days of your receipt of this letter stating what action you plan to take to bring these products into compliance with applicable requirements. If you no longer market any guaifenesin single ingredient extended release products or believe you have received this letter in error, please notify us of this fact. If appropriate corrective action is not undertaken, the FDA may initiate legal action without further notice. The Act provides for seizure of illegal products or injunction against the manufacturers and/or distributors of illegal products.

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Your response to this letter should be directed to the attention of Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Daniel Hauck
Alphagen Laboratories Inc
11525 North Fulton Industrial Blvd
Alpharetta, GA 30201

Products: Guaifenesin SR Tablets 1200 mg
Guaifenesin SR Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. David Ambrose
Ambi Pharmaceuticals
16206A Flight Path Dr
Brooksville, FL 34604

Products: Ambi 600 Caplets 600 mg
Ambi Caplets 600 mg
Ambi Caplets 800 mg
Ambi 1000 Caplets 1000 mg
Ambi 1200 Caplets 1200 mg

Dear Sir/Madam:

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David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Chadu Patel
Amide Pharmaceutical Inc
101 East Main St
Little Falls, NJ 07424

Products: Amibid LA Tablets 600 mg
Guaifenesin ER Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

Guaifenesin is a drug that presently has an established general recognition of safety and effectiveness under the OTC Monograph system as an expectorant (21 CFR 341), but the OTC monograph system does not include provisions for extended release dosage form drug products. The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations at section 310.502(a)(14), codifies the new drug status of extended release drug products. Therefore, single ingredient guaifenesin extended release drug products are new drugs and require an approved application for marketing.

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David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Steven Brown
Anabolic Inc
17802 Gillette Ave
Irvine, CA 92614

Products: Fenesin Tablets 600 mg
Muco Fen LA Tablets 600 mg
Muco Fen Tablets 1200 mg
Guaifenesin Tablets 1200 mg

Dear Sir/Madam:

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Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Hank Smith
Capellon Pharmaceuticals Inc
7462 Dogwood Park
Fort Worth, TX 76118

Products: Liquibid Tablets Sustained Release 600 mg
Liquibid Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Ms. Donna Radrik
Celltech Manufacturing Inc
755 Jefferson Rd
Rochester, NY 14603-1716

Products: Humibid LA Tablets 600mg
Humibid Pediatric Capsule 300 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Thomas Arington
Duramed Pharmaceuticals Inc
5040 Lester Rd
Cincinnati, OH 45213

Products: Guaifenesin Tablets Sustained Release 600 mg
Guaifenesin Tablets Sustained Release 1200 mg
Guaifenesin SR Caplets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Director
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Wyane Harris
Eckerd Drug Co
8285 Bryan Dairy Rd
Largo, FL 33777

Products: Humibid LA Tablets 600 mg
Liquibid Tablets Sustained Release 600 mg
Duratuss G Tablets 1200 mg
Liquibid Tablets Sustained Release 1200 mg

Dear Sir/Madam:

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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Ron Pressley
Ethex Corp
10888 Metro Ct
Saint Louis, MO 63043

Products: Guaifenex G Tablets 1200 mg
Guaifenex LA Tablets Extended Release 600 mg
Guaifenex RX Tablets Combo (kit)

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

President/Chairman of the Board/Chief Executive Officer
Iopharm Laboratories Inc
7549 Pebble Dr
Fort Worth, TX 76118

Products: Guaifenesin 1200 TR Tablets
Guaifenesin TR Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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WARNING LETTER

October 11, 2002

Mr. Ron Pressley
KV Pharmaceutical Co
2503 South Hanley Rd
Saint Louis, MO 63144

Products: Guaifenex G Tablets 1200 mg
Guaifenex LA Tablets 600 mg
Guaifenex RX Tablets Combo (kit)

Dear Sir/Madam:

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Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

President/Chairman of the Board/Chief Executive Officer
Mikart Inc
1750 Chattahoochee Ave NW
Atlanta, GA 30318

Products: Guaifenesin SR Tablrt 800 mg
Guaifenesin Tablets 1000 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

Guaifenesin is a drug that presently has an established general recognition of safety and effectiveness under the OTC Monograph system as an expectorant (21 CFR 341), but the OTC monograph system does not include provisions for extended release dosage form drug products. The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations at section 310.502(a)(14), codifies the new drug status of extended release drug products. Therefore, single ingredient guaifenesin extended release drug products are new drugs and require an approved application for marketing.

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Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Richard Reeves
Murfreesboro Pharmaceutical Nursing Supply
1843 Memorial Blvd
Murfreesboro, TN 37129

Products: Q Bid LA Tablets Sustained Release 600 mg
Guaifenesin Tablets 600 mg
Guaifenesin Tablets 600 mg
Q Bid LA Tablets 600 mg
Guaifenex G Tablets 1200 mg
Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

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David J. Horowitz, Esq.
Director
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Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Bhart Patel
Neil Laboratories Inc
55 Lake Rd
East Windsor, NJ 08520

Products: Guaifenesin SR Caplets 800 mg
Guaifenesin Caplets SR 1200 mg
Guaifenesin SR Caplets 1000 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Jack McCall
PDRX Pharmaceuticals Inc
727 North Ann Arbor Ave
Oklahoma City, OK 73127

Products: Guaifenesin LA Tablets 600 mg
Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Director
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Center for Drug Evaluation and Research
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Ms. Darlene Ryan
PFAB LP (Pharmafab)
2940 North Hwy, Suite 100
Grand Prairie, TX 75050

Products: Respa GF Tablets 600 mg
GFN Tablets 01 1200 mg
Guaifenesin SR Tablets 600 mg
GFN Tablets 06 600 mg
GFN Tablets 05 575 mg
GFN 600 Tablets 04 600 mg
GFN 1200 Tablets 05 1200 mg
GFN 1200 Tablets 1200 mg
GFN 600 Tablets 07 600 mg
GFN 600 Tablets 600 mg
GFN 800 Tablets 800 mg
GFN 1000 Tablets 1000 mg

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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Abelardo Acebo
Pharmakon Laboratories Inc
6050 Jet Port Industrial Blvd
Tampa, FL 33634

Products: Ambi 600 Caplets 600 mg
Ambi Caplets 800 mg
Ambi Caplets 1000 mg
Ambi Caplets 1200 mg
Ambi Caplets 600 mg

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Director
Office of Compliance
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Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Kenneth Graeler
Physicians Total Care Inc
5415 South 125th E Ave Ste 205
Tulsa, OK 74146

Products: Guaifenesin LA Tablets 600 mg
Humibid LA Tablets 600 mg
Duratuss G Tablets 1200 mg

Dear Sir/Madam:

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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. William S. Propst, Sr.
Qualitest Pharmaceuticals Inc
1236 Jordon Rd
Huntsville, AL 35811

Products: Guaifenesin Sustained Release Tablets 1200 mg
Q-Bid LA Tablets 600 mg
Drituss G Tablets 1200 mg

Dear Sir/Madam:

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David J. Horowitz, Esq.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Charles Trayal
RX PAK Div Mckesson HBOC
4971 Southridge Blvd Ste 111 115
Memphis, TN 38141

Products: Humibid LA Tablets 600 mg
Duratuss G Tablets 1200 mg

Dear Sir/Madam:

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David J. Horowitz, Esq.
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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. J.R. Chen
Sage Pharmaceutical
5408 Interstate Dr
Shreveport, LA 71109

Products: Muco Fen 800 Tablets 800 mg
Ru Tuss Tablets 800 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Director
Office of Compliance
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Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Larry Boos
Sovereign Pharmaceutical Inc
7590 Sand St
Fort Worth, TX 76118

Products: Sinumist SR Tablets 600 mg
Humavent LA Tablets 600 mg

Suaifenesin Tablets 1200 mg
Guaifenesin Tablets 1200 mg
Pneumomist Tablets 600 mg
Guaifenesin TR Tablets 600 mg

Numobid Tablets 675 mg
Liquibid 1200 Tablets Sustained Release 1200 mg
Liquibid Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

Guaifenesin is a drug that presently has an established general recognition of safety and effectiveness under the OTC Monograph system as an expectorant (21 CFR 341), but the OTC monograph system does not include provisions for extended release dosage form drug products. The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations at section 310.502(a)(14), codifies the new drug status of extended release drug products. Therefore, single ingredient guaifenesin extended release drug products are new drugs and require an approved application for marketing.

Before there was a New Drug Application (NDA) approved for a single ingredient guaifenesin extended release product, FDA did not expend scarce enforcement resources to address such unapproved drugs. However, on July 12, 2002, FDA approved NDA 21-282 covering the marketing of Mucinex 600 mg, a guaifenesin extended release tablet expectorant for patients 12 years and above. Other single ingredient extended release guaifenesin drug products, which are

new drugs, must be approved under an NDA or abbreviated new drug application (ANDA) as required by the Federal Food, Drug, and Cosmetic Act (the Act).

There are no approved applications under the provisions of Section 505 on file with the FDA for the previously listed products marketed by your firm. Therefore, the marketing of these products without an approved new drug application constitutes a violation of Section 505(a) of the Act.

We request that you reply within fifteen (15) days of your receipt of this letter stating what action you plan to take to bring these products into compliance with applicable requirements. If you no longer market any guaifenesin single ingredient extended release products or believe you have received this letter in error, please notify us of this fact. If appropriate corrective action is not undertaken, the FDA may initiate legal action without further notice. The Act provides for seizure of illegal products or injunction against the manufacturers and/or distributors of illegal products.

The previously identified violation is not intended to be an all inclusive list of violations at your facility. It is your responsibility to assure that your firm is in compliance with all established requirements.

Your response to this letter should be directed to the attention of Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

President/Chairman of the Board/Chief Executive Officer
ST International Inc
7155 East Kemper Rd
Cincinnati, OH 45249

Products: Guaifenesin Tablets 600 mg
Guaifenesin Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

Guaifenesin is a drug that presently has an established general recognition of safety and effectiveness under the OTC Monograph system as an expectorant (21 CFR 341), but the OTC monograph system does not include provisions for extended release dosage form drug products. The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations at section 310.502(a)(14), codifies the new drug status of extended release drug products. Therefore, single ingredient guaifenesin extended release drug products are new drugs and require an approved application for marketing.

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Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Richard Roberts
United Research Laboratories Inc
1100 Orthodox St
Philadelphia, PA 19124

Products: Guaifenesin LA Tablets 600 mg
Guaifenesin SR Tablets 1200 mg
Guaifenesin Tablets 1000 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. Vinod M. Chitalia
Vintage Pharmaceutical Inc
140 Vintage Dr
Huntsville, AL 35811

Products: Guaibid LA Tablets 600 mg
Guaifenesin Tablets Sustained Release 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

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