DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

October 11, 2002

Mr. John Q. Adams

Product: Humibid Capsules Pediatric 300 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid Capsules Pediatric 300 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Humibid Capsules Pediatric 300 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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

President/Chairman of the Board/Chief Executive Officer
Amerisource Health Services Corp
2550 John Glenn Ave Ste A
Columbus, OH 43217

Product: Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Humibid LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. William Poole
Biovail Pharmaceuticals Inc
808 Aviation Pky Ste 1400
Morrisville, NC 27560

Product: Fenesin Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Fenesin Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Fenesin Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Robert J. Edwards, Jr.
Boca Pharmacal Inc
6601 Lyons Rd Ste I-10
Coconut Creek, FL 33073

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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. Narendra N. Borkar
Caraco Pharmaceutical Laboratories Ltd
1150 Elijah Mcoy Dr
Detroit, MI 48202-3344

Product: Guaifenesin LA Tablets Sustained Release 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets Sustained Release 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets Sustained Release 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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. Kevin Raidy
Cheshire Pharmaceutical Systems
6225 Shiloh Rd Ste D
Alpharetta, GA 30005

Product: Guaifenesin Extended Release Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Extended Release Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Extended Release Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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. John McLaughlin
Compumed Inc
1517 Edward Ave
Harahan, LA 70123

Product: Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Humibid LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Razik Gonzalia
Corepharma LLC
215 Wood Ave
Middlesex, NJ 08846

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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
Cypress Pharmaceutical Inc
135 Industrial Blvd
Madison, MS 39110

Product: Guaifenesin Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets 1200 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets 1200 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Michael Greco
Dartmouth Pharmaceuticals Inc
38 Church Ave Ste 220
Wareham, MA 02571

Product: Touro EX Tablets 575 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Touro EX Tablets 575 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Touro EX Tablets 575 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Miguel Armengol
Direct Dispensing Inc
3123A North West 73rd St
Miami, FL 33147

Product: Guaifenesin ER Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin ER Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin ER Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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/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 B. Guinn
Dispensing Solutions Inc
3000 West Warner Ave
Santa Ana, CA 92704

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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

President/Chairman of the Board/Chief Executive Officer
Drug Distributors Inc/a.k.a. Peyton's Northern
1111 South Adams St
Bluffton, IN 46714

Product: Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Humibid LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Bernie Talley
DRX Pharmaceutical Consultants Inc
8135 North Monticello Ave
Skokie, IL 60076

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product without an approved new drug application constitutes a violation of Section 505(a) of the Act.

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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. Phillip Frost
Goldline Laboratories Inc
4400 Biscayne Blvd
Miami, FL 33137

Product: Guaifenesin ER Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin ER Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin ER Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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
H J Harkins Co Inc
513 Sandydale Dr
Nipomo, CA 93444

Product: Guaifenesin SR Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin SR Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin SR Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Michael Reicher
Halsey Drug Co Inc
125 Wells Ave
Congers, NY 10920

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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. Barry Rostholder
Heartland Repack Services LLC
4755 South Ave
Toledo, OH 43615

Product: Guaifenesin Tablets SR 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets SR 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets SR 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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 Denis
Ivax Laboratories
4400 Biscayne Blvd
Miami, FL 33137

Product: Muco Fen 1200 Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Muco Fen 1200 Tablets 1200 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Muco Fen 1200 Tablets 1200 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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Sincerely yours,

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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. Ronals J. Steinlauf
Jerome Stevens Pharmaceuticals Inc
60 Da Vinci Dr
Bohemia, NY 11716

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product without an approved new drug application constitutes a violation of Section 505(a) of the Act.

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/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
Kaiser FDN Health Plan Colorado
16601 East Centretech Pky
Aurora, CO 80011

Product: Guaifenesin Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product without an approved new drug application constitutes a violation of Section 505(a) of the Act.

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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. Jeff Kiel
Kiel Laboratories Inc
2225 Centennial Dr
Gainesville, GA 30504

Product: Guaifenesin Tablets Long Acting 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets Long Acting 600 mg, a single ingredient guaifenesin extended release product.

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. Jeff Kiel
Kiel Pharmaceuticals Inc
2225 Centennial Dr
Gainesville, GA 30504

Product: Guaispan Tablets Long Acting 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaispan Tablets Long Acting 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaispan Tablets Long Acting 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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

President/Chairman of the Board/Chief Executive Officer
Liberty Pharmaceuticals
6541 Crista Palma Dr
Huntington Beach, CA 92647

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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
Links Pharmaceutical
17802 Gillette Ave
Irvine, CA 92614

Product: Guaifenesin Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets 1200 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets 1200 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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
M G Acquistion LLC DBA PCA
8770 Guion Rd Ste G
Indianapolis IN 46268

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Rudolph Friedman
Major Pharmaceuticals Inc
31778 Enterprise Dr
Livonia, MI 48150

Product: Guaifenesin LA Caplets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Caplets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Caplets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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. Paul Sudhakar
Martec Pharmaceuticals Inc
1800 North Topping Ave
Kansas City, MO 64120

Product: Guaifenesin TR Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin TR Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin TR Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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
MCR American Pharmaceuticals Inc
120 Summit Pky 101
Birmingham, AL 35209

Product: Allfen Tablets 1000 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Allfen Tablets 1000 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Allfen Tablets 1000 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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

Dr. Richard Roberts
Mutual Pharmaceutical Co Inc
1100 Orthodox St
Phildelphia, PA 19124

Product: Guaifenesin Tablets LA 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets LA 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets LA 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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

Ms. Carolyn McPherson
National Pharmpak Services
3540 East Pike
Zanesville, OH 43701

Product: Duratuss G Tablet 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Duratuss G Tablet 1200 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Duratuss G Tablet 1200 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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
Nucare Pharmaceuticals Inc
622 West Katella Ave
Orange, CA 92867

Product: Guaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

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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. Robert Young
Pharmaceutical Utilization Management Program VA Inc
2560 Anderson Hwy Ste C
Powhatan, VA 23139

Product: Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Humibid LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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

Ms. Debbie Moody
Pharmacy Care Plus LC
303 Ashcake Rd Ste M
Ashland, VA 23005

Product: Guaifenex LA ER Tablet 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenex LA ER Tablet 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenex LA ER Tablet 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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

Mr. Steven Mead
Prestige Packaging Inc
24700 Crestview Ct.
Farmington Hills, MI 48335

Product: Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Humibid LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. D.S. Brar
Ranbaxy Pharmaceuticals Inc
600 College Rd East
Princeton, NJ 08540

Product: Guafenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guafenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guafenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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
Respa Pharmaceuticals Inc
213 South Milwaukee Ave
Lake Villa, IL 60046

Product: Respa-GF Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Respa-GF Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Respa-GF Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Hugh Campbell
Seatrace Pharmaceuticals Inc
503 Hickman St
Rainbow City, AL 35906

Product: GUA SR Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of GUA SR Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for GUA SR Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Paul Cotpon
Sidmak Laboratories Inc
17 West St
East Hanover, NJ 07936

Product: Guaifenesin Tablets Extended Release 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets Extended Release 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets Extended Release 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements. If you no longer market a guaifenesin single ingredient extended release product 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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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
Southwood Pharmaceuticals Inc
3860 Del Amo Blvd #404
Torrance, CA 90503

Product: Cuaifenesin LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Cuaifenesin LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Cuaifenesin LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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
Stewart Jackson Pharmacal Inc
4200 Lamar Ave
Memphis, TN 38118

Product: Bidex Tablets 1000 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Bidex Tablets 1000 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Bidex Tablets 1000 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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. Arnaldo La Luz
Thrift Drug Services
Caguas Rd KM 21.1 Rt 1
Guaynabo, PR 00928

Product: Duratuss G Tablets 1200 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Duratuss G Tablets 1200 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Duratuss G Tablets 1200 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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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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
UBC Pharma Inc
1950 Lake Park Dr
Smyrna, GA 30080

Product: Duratuss G Tablets

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Duratuss G Tablets, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Duratuss G Tablets as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

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/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. Kevin B. Shaw
Vangard Labs Inc
835 North L Rogers Wells Blvd; PO Box 1268
Glasgow, KY 42142-1268

Product: Guaifenesin Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Guaifenesin Tablets 600 mg, a single ingredient guaifenesin extended release product.

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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There is no approved application under the provisions of Section 505 on file with the FDA for Guaifenesin Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

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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. Lee Scott
Wal Mart Stores Inc
1201 Moberly Lane
Bentonville, AR 72716

Product: Humibid LA Tablets 600 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of Humibid LA Tablets 600 mg, a single ingredient guaifenesin extended release product.

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 is no approved application under the provisions of Section 505 on file with the FDA for Humibid LA Tablets 600 mg as marketed by your firm. Therefore, the marketing of this product 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 this product into compliance with applicable requirements.

If you no longer market a guaifenesin single ingredient extended release product 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