

Food and Drug Administration
Rockville MD 20857

AUG 18 2000

TRANSMITTED VIA FACSIMILE

Ms. Mary Jane Nehring
Director, Worldwide Regulatory Affairs
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

RE: NDA# 19-658
Claritin (loratadine) Tablets
NDA# 20-704
Claritin (loratadine rapidly-disintegrating tablets) RediTabs
NDA# 20-641
Claritin (loratadine) Syrup
NDA# 20-470
Claritin-D 24 Hour (10 mg loratadine/240 mg pseudoephedrine sulfate)
Extended Release Tablets
MACMIS ID#: 9224

Dear Ms. Nehring:

This letter concerns Schering Corporation's (Schering) dissemination of two direct-to-consumer (DTC) print advertisements for Claritin (loratadine) Tablets, Claritin (loratadine rapidly disintegrating tablets) RediTabs, Claritin (loratadine) Syrup, and Claritin-D 24 Hour (10 mg loratadine/240 mg pseudoephedrine sulfate) Extended Release Tablets (i.e., magazine wrap CRM1228). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these ads and concluded that they are misleading and violate the Federal Food, Drug, and Cosmetic Act and applicable regulations and should be discontinued immediately. Specifically, we refer to the magazine ads appearing as part of the front and back wrap covers of a recent issue of *health* periodicals.

The full-product Claritin ad appears as a back-to-back combination reminder/help-seeking ad. On the front of the magazine wrap is a Claritin reminder ad ("Joan Lunden Asks: Curious About Claritin? Ask your doctor's advice today."). This reminder ad is immediately followed by a help-seeking ad on the inside front of the magazine wrap ("Joan Clears the Air About Seasonal Allergies—4th in a Series: Reading, Writing, and Ragweed"). These back-to-back reminder/help-seeking ads convert the entire presentation into one full-product ad for Claritin that includes the product indication and several claims about the effect of allergies on school attendance and

great food • real beauty • total wellness

health

PERIODICALS



Joan Lunden Asks:
**Curious
About
CLARITIN®?**

Ask your doctor's
advice today.

Claritin®

10 mg
TABLETS (loratadine)

Available by prescription only.

Joan Clears the Air About Seasonal Allergies

4th in a Series: Reading, Writing, and Ragweed



Joan Lunden

Why seasonal allergies multiply your child's chances of missing school.

When autumn allergies start, so do sneezing and sniffing for more than 12 million school-age children. In fact, 2 million kids miss roll call each year because of seasonal allergies. That's an average of 10,000 empty classroom seats every day. Left untreated, your child's allergies can lead to more serious illnesses and more absenteeism. Learning the most you can about allergies and their treatment helps you help your child get the most out of school.

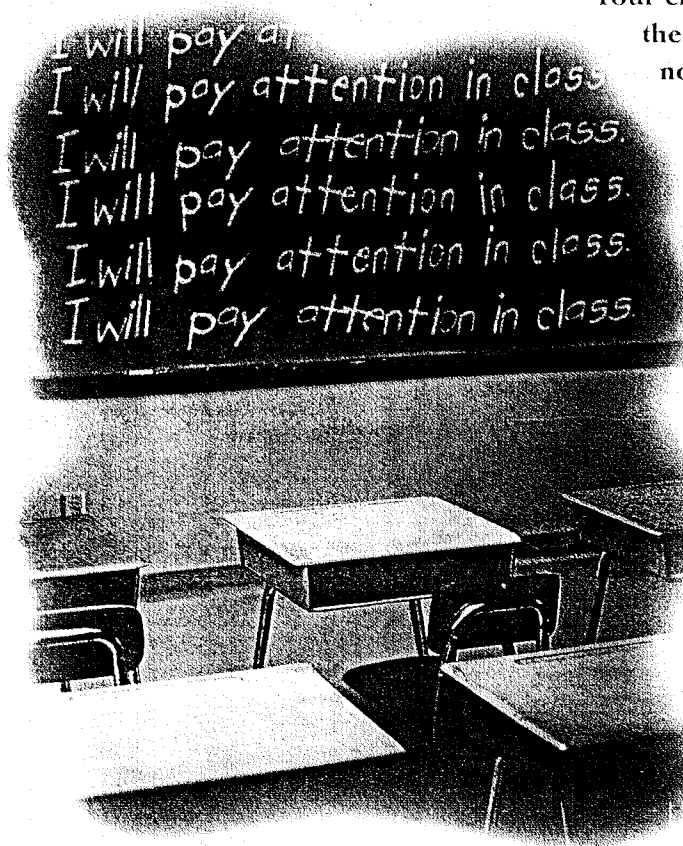
If your child is snoozing through math class, it could be from drowsy allergy medication.

It's tough enough for children to pay attention when their allergies are acting up. Their symptoms

difficult for them to stay alert. Fortunately, your child's doctor can prescribe allergy medications that will relieve your child's symptoms without drowsy side effects.

Your child's doctor has the right answers about nondrowsy relief.

Like all parents, I want what's best for my children, especially when it concerns their health. So when my daughter, Lindsay, kept sneezing and sniffing, we visited her doctor. He said seasonal allergies were the cause. (Like mother, like daughter.) Once he prescribed a medication that wouldn't make her drowsy, she felt better and so did I. Talk to your child's doctor today.



alone can make them tired and uncomfortable. Adding an over-the-counter antihistamine to the equation makes it even more

Visit www.allergylearninglab.com

Joan Clears the Air About Seasonal Allergies

5th in a Series: Controlling Congestion



Joan Lunden

Why feeling stuffy is a secret you don't want to keep.

Most allergy sufferers feel it. But few of them talk about it—nasal stuffiness or

congestion. When you're stuffed up, it's hard for you to breathe.

You may even lose your senses of taste and smell or have trouble sleeping through the night. So sharing your experience with

your doctor can really open your eyes and your stuffy nose. Only your doctor has prescription allergy medications that cover congestion, too. That way, you can breathe easier right away. If you're feeling stuffy, tell your



doctor about it. He or she has the relief that's right for you.

Your doctor can clear things up.

All seasonal allergy medicines aren't the same. Some just

address symptoms such as sneezing, runny nose, and red, itchy, watery eyes. Others have an added medication to unblock your stuffy nose. If you're congested, it's something you should tell your doctor. Your

doctor can prescribe medications that keep all these symptoms in check for 24 hours. So you can feel relief

throughout the day without nodding off. And you can rest more without nasal stuffiness. Talk to your doctor about congestion relief today.

Visit www.allergylearninglab.com

Schering / **KEN**

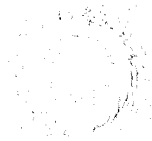
FIND OUT IF OUR FAMILY IS RIGHT FOR YOURS.



Claritin[®]
10 mg (loratadine)
TABLETS



Claritin-D[®] 24 Hour
(10 mg loratadine/240 mg pseudoephedrine sulfate, USP)
Extended Release Tablets



Claritin RediTabs[®]
10 mg (loratadine rapidly-disintegrating tablets)



Claritin Syrup
(loratadine) 10 mg per 10 mL

Talk to your doctor about the CLARITIN family of medications.
And call 1-800-CLARITIN (1-800-252-7484)
for a \$5.00 rebate certificate and additional important information. Or visit www.claritin.com

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