

Food and Drug Administration Rockville MD 20857

AUG 1 8 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

Ms. Mary Jane Nehring Schering Corporation NDA#: 19-658, 20-704, 20-641, 20-470

children's attention spans. This full-product ad is misleading because it fails to provide any risk information relating to side effects and contraindications (including warnings and precautions) to balance the effectiveness claims. In addition, this ad contains unsubstantiated implied claims that Claritin will impact school attendance and children's attention spans. Furthermore, the ad does not include an accompanying brief summary of risk information as required by the advertising regulations.

Similarly, the other full-product Claritin ad appears as a back-to-back combination help-seeking/reminder ad. On the inside back of the magazine wrap is a help-seeking ad ("Joan Clears the Air About Seasonal Allergies—5th in a Series: Controlling Congestion"). This help-seeking ad is immediately followed by a Claritin product line reminder ad ("Find Out If Our Family is Right For Yours... Talk to your doctor about the Claritin family of medications") on the back cover of the magazine wrap. Again, these back-to-back help-seeking/reminder ads convert the entire presentation into one full-product ad for Claritin-D 24 Hour that includes the product indication but omits fair balance and the required accompanying brief summary of risk information.

Schering should immediately cease disseminating and using promotional materials for Claritin and Claritin-D 24 Hour that contain the same or similar claims or presentations. We should receive your written response no later than September 1, 2000, and it should list similarly violative materials, with a description of your method of discontinuation, and the discontinuation date.

Your response should be directed to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Schering that only written communications are considered official.

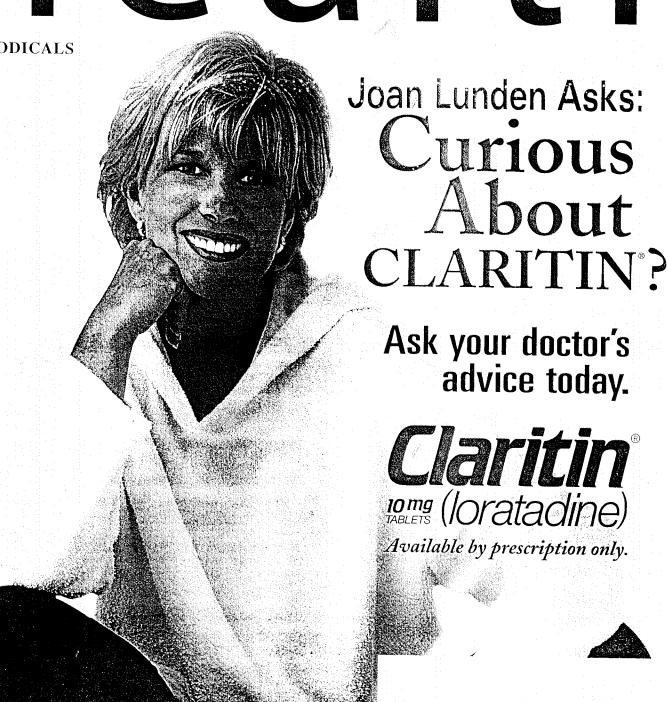
In all future correspondence, regarding this matter, please refer to MACMIS ID# 9224 in addition to the NDA number.

Sincerely,

/S/

Joan Hankin, JD Consumer Promotion Analyst Division of Drug Marketing, Advertising, and Communications





Joan Clears the Air About Seasonal Allergies

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



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.

Joan Lunden

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

Sec. 3553

When autumn allergies start, so do sneezing and sniffling 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.

I will pay an I will pay attention in class. I will pay attention in class.

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

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 sniffling, 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.

Visit www.allergylearninglab.com

Schering | KEY

Seasonal Allergies

5th in a Series: Controlling Congestion



Joan Lunden

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

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

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

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

Your doctor can clear things up.

All seasonal allergy medicines

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 / 11=11

FIND OUT IF OUR FAMILY IS RIGHT FOR YOURS.





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



Claritin RediTabs

10mg (loratadine rapidly-disintegrating tablets)



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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Available by prescription only.