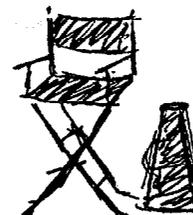


DIRECTORS GUILD OF AMERICA - PRODUCER PENSION AND HEALTH PLANS

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MATTHIAS F. ERIEG
Administrator

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September 12, 2001

Barnard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14-71/HF-1
Rockville, MD 20857

Dear Dr. Schwetz:

We are writing to support Blue Cross of California's Citizen Petition to the Food and Drug Administration requesting that Allegra, Claritin and Zyrtec be switched from prescription status to over-the-counter. These drugs are available without prescription, at a significant cost savings, in nearly every industrialized country. It is our understanding that there is no evidence-based reason for these medications to remain prescription status.

Allegra, Claritin and Zyrtec are safer than the currently available over-the-counter allergy medications. They have low incidence of adverse reactions, few side effects and little potential for harm if they are not used correctly. They do not need the safeguards of prescription status. On the other hand, many currently available over-the-counter allergy medications have side effects such as drowsiness, dizziness and blurred vision, making it difficult for users to perform otherwise routine tasks such as driving a car.

Switching Allegra, Claritin and Zyrtec to over-the-counter status will allow uninsured and underinsured allergy sufferers to purchase safer drugs. Uninsured Americans cannot typically pay \$85 for a 30-day supply of allergy medication. For those who are fortunate enough to have pharmacy coverage, the alarming rate of increase in their insurance premiums is due in large part to unwarranted pharmaceutical costs. Switching these drugs to over-the-counter status will save Americans millions in unnecessary healthcare costs.

We agree with Blue Cross of California that the FDA has authority to switch these medications to over-the-counter status. We strongly encourage you to take this action as soon as possible. Copies of this letter are also being submitted to Docket No. 98P-0610/CP1.

Sincerely,

Matthias F. Erieg
Administrator

98P-0610

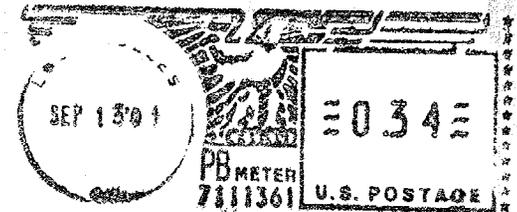
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cc: Docket No. 98P-0610/CP1 (3 copies)
Dockets Management Branch, FDA

Honorable Bradley J. Sherman
U.S. House of Representatives

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PENSION AND HEALTH PLANS**

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