



# Blue Cross of California

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January 12, 1999

Director of Regulatory Affairs  
Schering-Plough Corp.  
2000 Galloping Hill Road  
Kenilworth, NJ 07033-0530

Dear Sir or Madam:

On July 24, docket number 98P-0610/CP was filed with the Food and Drug Administration under the Code of Federal Regulations, Food and Drug Administration, Title-21, section 10.30. This regulation provides that drugs limited to prescription use under an NDA can be exempted from that limitation if the FDA determines the prescription requirements to be unnecessary for the protection of public health. My letter specifically petitions the FDA to convert non sedating antihistamines to OTC regulatory status.

Currently, the Federal Food and Drug Administration (FDA) authorizes over 100 different antihistamine and antihistamine/decongestant combinations for over-the-counter (OTC) sale. Although considered safe and effective by the FDA, all OTC antihistamine and combination antihistamine/decongestant combinations are non-selective and have a more significant sedative and anticholinergic effect than the three leading prescription antihistamine and antihistamine/decongestant products. Your safest antihistamine and antihistamine/decongestant combination medications are available only by a prescription in the United States and are described below:

Claritin (5 mg loratadine)

Claritin DS (10 mg loratadine)

Claritin-D (5 mg loratadine, 120 mg pseudoephedrine)

Claritin-D 24 Hour (10 mg loratadine, 240 mg pseudoephedrine)

Claritin syrups

Maintaining Claritin and Claritin-D products as prescription drugs only, while their more dangerous antihistamine and antihistamine/decongestant alternatives are available without a prescription, deprives a majority of patients ready access to quality pharmaceutical care. This lack of access results in a greater incidence of side effects associated with the current OTC alternatives, adding considerable unnecessary medical costs to the health care system. The following information is provided to validate the petition and medical rationale for the conversion of Claritin and Claritin-D products to OTC status:

- Of the 3.5 billion health problems treated annually, almost 2 billion, or 57%, are treated with OTC drugs as primary or major adjunctive therapy. The current restrictions limiting OTC access to antihistamine and antihistamine/decongestant medications with a higher incidence of sedation and anticholinergic side effects is dangerous and costly.

98P-0610

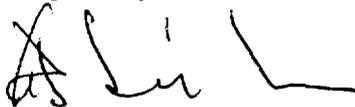
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- Americans are 4 times as likely to purchase an OTC medication than they are to consult a physician. Many patients can not afford the office visit associated with a physician's visit. The current restrictions precluding OTC access to antihistamine and antihistamine/decongestant medications with a lower incidence of side effects predisposes many patients to dangerous antihistamine and antihistamine/decongestant treatment options.
- Almost 60% of all dosage units consumed by patients are for OTC medications. The current restrictions precluding OTC access to antihistamine and antihistamine/decongestant medications with a lower incidence of side effects limits many patients to dangerous antihistamine and antihistamine/decongestant treatment options.
- Over 500 medical conditions are treatable with one or more OTC medications as the primary therapy or major adjunctive therapy. These conditions occur millions of times each year (e.g. cold, allergy, and nasal congestion). The current restrictions precluding OTC access to Claritin and Claritin-D products, which have a lower incidence of side effects, predisposes many patients to dangerous antihistamine and antihistamine/decongestant treatment options for the self treatment of many of these conditions.
- Requiring that a patient schedule an office visit to obtain safe medications such as Claritin and Claritin-D products is an undue time and financial burden to the patient. Additionally, requiring a prescription for these safe antihistamine and antihistamine/decongestant combinations trivializes the patient physician relationship.
- Claritin and Claritin-D products as exclusive ingredients and in their decongestant combinations have been reviewed and approved by the Canadian and European equivalents to the FDA as direct to OTC approvals, bypassing the prescription requirement process.

Patients are seeking greater ownership of their health care and often prefer to self medicate when feasible. Of all the therapeutic classes of drugs available, the discrepancy in safety between the antihistamine and antihistamine/decongestant combinations available OTC compared to prescription Claritin and Claritin-D products is most pronounced. Based on the information provided above, it is logical that Claritin and Claritin-D products be immediately converted to OTC medication status.

Schering-Plough's direct to OTC approvals for Claritin and Claritin-D products in Canada and Europe are particularly relevant to my petition. At this point in the FDA review process, it is appropriate that the United States Food and Drug Administration have access to your New Drug Submissions in Canada and Europe for the OTC forms of Claritin and Claritin-D products. To help ensure a timely review of my petition, please expedite a summary of these documents to my attention within 30 days of your receipt of this letter.

Respectfully,



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CC: Douglas Schur, Esquire, WellPoint Health Networks  
Andrea Masciale, Regulatory Policy Division, FDA