



PROVIDER SERVICE NETWORK

Affiliated with

CAREGROUP HEALTHCARE SYSTEM

Lahey CLINIC

August 29, 2001

Sandra L. Titus
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5630 Fishers Lane, Room 1093
Rockville, MD 20857

Rec'd 9/6/01 16

Dear Ms Titus:

We are writing to document our support of FDA Docket #98P-0610, submitted by Blue Cross of California, to grant nonprescription (OTC) status to three popular prescription antihistamines (i.e., Allegra, Claritin, and Zyrtec) which has subsequently been unanimously supported by the FDA Nonprescription Drugs and Pulmonary and Allergy Drugs Advisory Committees. Clearly, these products meet all of the requirements for OTC status and have a long history of OTC marketing around the world.

The Provider Service Network (PSN) is a Medical Service Organization (MSO) in Boston, Massachusetts. We represent approximately 3,000 practicing physicians affiliated with institutions including the Beth Israel Deaconess Medical Center, New England Baptist Hospital, Mount Auburn Hospital, Deaconess Waltham Hospital, Deaconess Nashoba Hospital, Deaconess Glover Hospital, Lahey Clinic Hospitals, and other community-based medical group practices. In total, our physicians serve over one million patients and we strive daily to provide care of the highest possible quality and cost-efficiency. Accordingly, our PSN Pharmacy and Therapeutics (P&T) Committee created a Universal Drug Formulary (i.e., a preferred drug list) for our physicians to guide them in prescribing cost-effective prescription and nonprescription medications for our patients.

The medical literature has clearly documented the safety and efficacy of the non-sedating antihistamines, such as Claritin and Allegra. In fact, the very same pharmaceutical companies that are now opposed to this change to OTC status have proved these non-sedating prescription drugs "safer" than their nonprescription sedating antihistamines. Ironically, these same manufacturers advertise this fact regularly to consumers via their direct-to-consumer (DTC) advertising.

Historically, the changeover to OTC status has generally resulted in increased drug accessibility for patients, along with tremendous cost savings for both consumers and the health care system overall. Last year, the class of non-sedating antihistamines generated sales of approximately \$4.7 billion, and insurance providers paid for much of that amount. As a health care system that is "at-risk" for pharmacy costs we admittedly would benefit financially from this change. However, so too would the millions of patients who do not presently have prescription drug insurance coverage, as well as those senior patients who presently have limited to no Medicare coverage for prescription products such as these. Meanwhile, the manufacturers would continue to profit from the OTC sales of these products and the overall volume of these products sold to consumers may even increase.

On behalf of our entire network of providers, we urge the FDA to act quickly in transitioning these products to an OTC status at the same dosage strengths now available by prescription. We feel that it would be in the best interest of all parties, and we thank you for your consideration of this matter.

Sincerely,

[Handwritten signature of Jordan Busch]

[Handwritten signature of Neil Minkoff]

Jordan Busch, M.D.
Beth Israel Deaconess Physician Organization,
PSN P&T Committee Co-Chair

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