CITIZEN OUTREACH

"Putting the Public Back in Public Policy"

611 Pennsylvania Avenue, SE, #439 ◆ Washington, DC 20003-4303

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March 21, 2003

Mark McClellan, M.D.
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Docket # 02P - 0168

Dear Commissioner McClellan,

I am writing today regarding a matter currently under your consideration, a request by WellPoint Health Network to switch a number of prescription antihistamines to over-the-counter status. It is my understanding that such a request by a for-profit insurance provider is unprecedented and I'm writing to express serious concerns about granting such a request.

As an allergy sufferer myself, I'm all for making relief provided by certain drugs as widely and cost-effectively available as possible; however, the safety of the consumer using such products is a responsibility not to be taken lightly.

While Claritin has been on the market for quite some time and has the benefit of being tested and evaluated properly, some of the other antihistamines under consideration have been on the market for a considerably shorter period of time. Making these drugs available without a prescription before sufficient review and evaluation has been made is problematic. Just consider the current problems and concerns regarding the untested and unmonitored use of ephedra.

I'm also deeply suspect of the motivations of the petitioner.

Switching this class of drugs means WellPoint and other providers will no longer have to cover them in policies, nor will they have to cover the costs of the doctor visits necessary to obtain the prescriptions. While I can understand how moving these drugs to OTC status will benefit WellPoint from a financial point of view, I can't see how it benefits the

consumer or patient. The effect of the petition would appear to be that consumers will have easier access to drugs not fully tested in the marketplace yet at a higher out-of-pocket expense.

I am also troubled by the precedent such a decision by the FDA could set.

If the for-profit health insurers are successful with this petition, it will open up a Pandora's box of new and additional petitions based solely on the health of the insurers' bottom line and not the heath of the insured. What may seem like a minor request today involving a few allergy medicines has the potential for developing into a huge health-care rationing problem in what well could be life-and-death situations down the road.

For these reasons I therefore respectfully urge you to deny the petition by WellPoint Health Networks in this regard and maintain the current, established procedures of the FDA for considering the wise and safe switching of medications to over-the-counter status.

Sincerely yours,

Chuck Muth
President
Citizen Outreach

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services

Food and Drug Administration
5600 Fishers Lane
HFD-240, Room 12B-05
Rockville, MD 20857

April 8, 2003

Chuck Muth
Citizen Outreach
611 Pennsylvania Ave., SE
#439
Washington, D.C. 20003-4303

Dear Mr. Muth:

Thank you for your letter dated March 21, 2003, to the Food and Drug Administration (FDA) concerning prescription to over-the-counter (OTC) switching of several antihistamines. Your letter was forwarded to the Center for Drug Evaluation and Research (CDER), one of the five centers within the Food and Drug Administration (FDA), for reply.

We are always interested in comments from consumers. Public participation at the FDA is a two-way process through which the Agency communicates priority health information to the public and the public communicates their views, attitudes, reactions, and knowledge to the FDA.

At the present time, Docket No. 02P-0168 is not open for comments. I will, however, forward your comments to the Dockets Management Branch where your letter will be kept on file. I will also forward a copy of your letter to the Division of Over-The-Counter Drug Products so the staff will be aware of your concerns.

Thank you for writing to the FDA. Please do not hesitate to contact me if I can provide assistance in the future.

Sincerely,

Joan Powers
Consumer Safety Officer
Division of Drug Information, HFD-240
Office of Training and Communications
Center for Drug Evaluation and Research

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