



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

JUN 29 2001 01 JUL 10 12:19  
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The Honorable Terry Everett  
House of Representatives  
Washington, D.C. 20515-0102

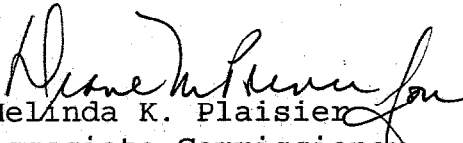
Dear Mr. Everett:

Thank you for your letter of May 24, 2001, on behalf of your constituent, Mr. Steven F. McCarthy of Montgomery, Alabama, regarding concerns about switching allergy medications from prescription to over-the-counter status.

Currently, the Food and Drug Administration (FDA or the Agency) has an open docket to receive comments on these prescription allergy drugs of concern to your constituent. We are forwarding your letter to docket number 98P-0610 where it will be considered by the Agency.

Thanks again for contacting us concerning this matter. If you have further question, please let us know.

Sincerely,

  
Melinda K. Plaisier  
Associate Commissioner  
for Legislation

cc: Dockets Management, HFA-305  
(Docket No. 98P-0610)

98P-0610

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TERRY EVERETT  
2D DISTRICT, ALABAMA

COMMITTEE ON VETERANS' AFFAIRS

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MILITARY READINESS



Congress of the United States  
House of Representatives  
Washington, DC 20515-0102

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OPP, AL 36467  
(334) 493-9253

May 24, 2001

Ms. Melinda K. Plaisier  
Associate Commissioner for Legislation  
Food and Drug Administration  
Room 1555  
5600 Fishers Lane  
Rockville, MD 20857

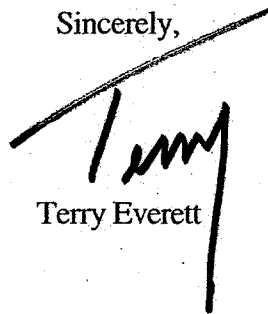
RE: Allergy medications Rx to OTC switch  
Mr. Stephen F. McCarthy, 3017 Ivy Chase Loop, Montgomery, Alabama 36117

Dear Ms. Plaisier:

Enclosed is correspondence from my constituent, above, about his concerns over proposals to switch some prescription allergy medications to approve over the counter sales. Mr. McCarthy pointed out that the FDA should consider the effect this would have on consumers who have prescription drug coverage, but live on fixed incomes.

I will appreciate your affording Mr. McCarthy all due and appropriate consideration under the law, and any information you are able to provide. I will be grateful if you will respond to me at my Washington office in a form that I may share with Mr. McCarthy. My address is 2312 Rayburn Building, Washington DC 20515. My Washington office fax number is (202) 225-8913. If it is more convenient to telephone, please speak to Victoria Ebell of my staff at (202) 225-2901. Thank you for your kind assistance.

Sincerely,



Terry Everett

TE/ve

Enclosure

Web Site: <http://www.house.gov/everett>

E-Mail: [Terry.Everett@mail.house.gov](mailto:Terry.Everett@mail.house.gov)

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11-2832

**Everett, Terry**

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**From:** Everett, Terry  
**Sent:** Wednesday, May 16, 2001 10:10 AM  
**To:** 'Steve McCarthy'  
**Subject:** RE: Drug company SWINDLE !!!

Steve - Send me a copy of the article along with your mailing address to 2312 Rayburn Building, Washington, D.C. 20515.

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**From:** Steve McCarthy  
**Sent:** Sunday, May 13, 2001 3:52 PM  
**To:** Everett, Terry  
**Subject:** Drug company SWINDLE !!!

Dear Mr. Everett, I would like to bring to your attention an article written in The Montgomery Advertiser this past week and request that you look into this matter for me. The article referred to a major insurance company that had requested the FDA remove certain drugs from the prescription drug list and have them changed to over-the-counter drugs. The insurance company cited how much money they could save by acting on their request. I also read that the FDA had tentatively approved this. All this is being done in a manner which should be illegal, giving no consideration to older adults on fixed incomes and still needing to keep our supplemental insurance in force because of the rising costs of medical care and the lack of our government to ensure that it is provided. Please look into this matter and do what you can to stop it before it is too late.  
Respectfully, Steve McCarthy

Dear Mr. Everett,

Montgomery, Al

Enclosed is the article wick I refered to in my e-mail request to you earlier this week. I hope that you can check it out and let me know of the final outcome. I certainly appreciate you doing this for me.

Thank You  
Steve McCarthy

*Stephen F McCarthy*

Trip Page 2A 1

# Allergy drugs may get shelf space

The Associated Press

GAITHERSBURG, Md. — Three popular allergy medications are safe enough to be sold without prescription, a federal advisory panel ruled Friday in an unprecedented case that could save the health insurance industry billions of dollars but increase costs for consumers.

Working on a report by WellPoint Health Networks of Thousand Oaks, Calif., the good-old-Drugs Administration panel recommended that Claritin, Allegra

and Zyrtec be made available over the counter, without supervision by a doctor.

The vote was 19-4 for Claritin and Zyrtec, and 18-5 for Allegra. The FDA is not required to follow the recommendations of the panel, but usually does so.

Dr. John Jenkins of the FDA said he did not have a timeframe for a decision in the "very unusual" case. Traditionally drug companies, not insurance companies, ask for a change, he said.

WellPoint, which could save \$45 million a year, had

## on the Web

► Food and Drug Administration: [www.fda.gov](http://www.fda.gov)

argued that the allergy medications were safe.

"There is no clinical reason for Claritin, Allegra and Zyrtec to be maintained as prescription drugs," Robert Seidman, a company vice president, told the 23-member panel. "They have side effects similar to a sugar pill."

Drug companies coun-

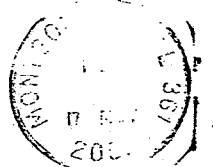
tered that the move would force consumers into a "risky trial-and-error gamble with their health, their quality of life and their money."

Dr. Robert J. Spiegel, vice president of Schering-Plough, maker of Claritin, said prescriptions are needed to "protect and optimize the public health."

"Insurance companies see a physician visit as a cost item," he said. "We see it as an essential part of health care. Now is not the time to drive patients farther away from their physicians."

advertiser.com

*Steve McCarthy  
3017 Ivy Chase Loop  
Montgomery, Al 36117*



*Rep. Jerry Everett*

ington, DC  
Everett, M.C.