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The Hazards of Seldane

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Allergy sufferers who take Seldane could easily be confused by recent actions of the Food and Drug Administration. Less than two weeks after the agency approved a generic form of the popular antihistamine, the agency has moved to take the original drug off the market. But the proposed ban against Seldane comes after years of warnings about its potential hazards. Removing it from the market is thoroughly justified.

Introduced in 1985, Seldane was the first prescription antihistamine to relieve symptoms of allergies like sneezing, itching and runny nose without causing drowsiness. But within a few years, serious problems were reported. When taken with certain antibiotics and anti-fungal drugs, Seldane apparently could trigger irregular heart rhythms.

Over the years the F.D.A. received about 40 reports of serious heart rhythm abnormalities, evidently caused by Seldane, that led to eight deaths. But the agency, which is supposed to insure that drugs are safe and effective, felt that Seldane should remain on the market because, for a time, it was the only such drug available and because the benefits of an antihistamine that did not cause drowsiness, a potential hazard itself, were thought to outweigh the risks.

The F.D.A. issued warnings to doctors about potential side effects when Seldane was simultaneously prescribed with other drugs. Additional warnings to doctors, pharmacists and the public came from Seldane's manufacturer, Hoechst Marion

Roussel. But while dangerous incidents have decreased, they have not been eliminated.

Last July Hoechst Marion Roussel received F.D.A. approval to market another antihistamine, called Allegra, which consists of the primary active derivative of Seldane. Since Allegra does not pose the same risk of abnormal heart rhythms, it could easily be substituted for Seldane, but the agency wanted to be certain that no other serious risks became evident after widespread use of Allegra.

After nearly six months on the market, Allegra has not presented any surprises. But in a classic bureaucratic coincidence, as the new drug was being marketed, an application for a generic form of Seldane made it through the agency's drug approval apparatus and was routinely approved earlier this month.

Now, deeming the trial period for Allegra sufficient, the F.D.A. proposes to ban both Seldane and its generic substitute. The manufacturers have 30 days to respond, and the hearing process could last a year as both sides present scientific evidence. Hoechst Marion Roussel has indicated that it will fight the ban, challenging the agency's judgment on the safety of Seldane. That may be an understandable business strategy, but the better public health strategy would be to market Allegra more aggressively and let Seldane be withdrawn more quickly.

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