

HHS NEWS

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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(Food and Drug Administration)
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The Food and Drug Administration today announced that Eli Lilly & Co. is recalling supplies of its arthritis drug Oraflex from pharmacy shelves and advising pharmacists and physicians, by letter, to halt the drug's use.

Distribution of the arthritis drug was suspended worldwide by Lilly last night after the United Kingdom halted its sale as a result of 61 deaths possibly associated with the product there. The U.K. suspension is for 90 days.

Lilly is also providing an address to which patients may send unused portions of Oraflex (benoxaprofen) for refund. The address is:

Eli Lilly & Co.
1202 South Dakota St.
Building #80
Indianapolis, Ind., 46225

The drug has been in use in the United Kingdom for approximately two years and in the United States for about three months. After its U.S. approval April 19, 12 deaths from liver and kidney failure were reported in the United Kingdom. All were among elderly persons at the highest dosage (600 mg.).

U.S. recommendations that elderly persons be started on a daily dose of half or two thirds that dose were emphasized in June in a boldface section of revised labeling and in letters from Lilly to all physicians.

The drug has been marketed in South Africa, Spain, Germany, Taiwan and Denmark, as well as in the U.K. and U.S. Earlier this week, Denmark had limited the drug to hospital use.

In the United States, wholesalers and pharmacists are being notified by Lilly, and FDA has approved a letter to physicians to be distributed by the company.

FDA's continuous review of serious reactions in the United States includes

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investigations of 11 deaths that may be associated with the drug. The United Kingdom pattern of deaths from liver and kidney failure has not been observed here, however.

After the initial 12 reports of death in the United Kingdom, the British registry of adverse effects turned up an additional 33 deaths of persons associated with benoxaprofen. Seventeen of these were due to gastrointestinal hemorrhage or perforated ulcers.

Suspension of sales was jointly announced last night by Lilly and Health and Human Services Secretary Richard S. Schweiker and FDA Commissioner Arthur Hull Hayes, Jr., M.D.

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