

Mrs. Louis C. Setter
39955 Golfers Drive
Palmdale, CA 93551

3-7-01

Sir:

The proposed emblem to alert those to potentially serious side effects from drugs is a lifesaving need. To say only 3 or 4 deaths occurred from any drug is far too many. As an RN I know far too many victims. Those that push the FDA to rush to market drugs risk this tragedy. Please add this safety warning.

Sincerely
Ruch & Setter RN

Prescription

Continued from S1

three years. Experts know that unanticipated reactions occur most frequently in newly marketed drugs. This emblem, which is in use in Great Britain, will serve as a signal to doctors to use extra care, and to be on the lookout for rare but potentially serious side effects.

The FDA plans to phase in changes, with the novel labels making their debut within the next year on new drugs. The new labels will be gradually added to

drugs already on the market after that.

The agency is still soliciting comments on the proposed changes. If you want to weigh in, the deadline is March 22. The proposed changes are available on FDA's Web site: www.fda.gov/ohrms/dockets/98fr/122200a.htm.

Or you can submit written comments to Dockets Management Branch (HFA-305), Docket Number: 00N-1269, Food and Drug Administration, 5530 Fishers Lane, Room 1061, Rockville, MD 20857.

* and nurses use patients

00N-1269

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Dockets Management Branch
(HFA-305)

Food and Drug Administration

5530 Fishers Lane

Rockville MD 20857

Room 1061

Docket # OON-1269

