

NKF National Kidney Foundation

Making Lives Better

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November 12, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

Dear Sir or Madam:

The National Kidney Foundation (NKF) is responding to the Proposed Rule, "Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling," (**Docket No. 77-N-094I**), that was published in the *Federal Register* on August 21, 2002.

NKF urges the Food and Drug Administration to proceed with the proposal that the consumer labeling for OTC ibuprofen should have a warning directed at those at risk for the development of acute kidney failure associated with the use of the product. In 15 years of non-prescription use of ibuprofen, there have been 94 cases of kidney failure, including nine deaths and nine patients who required dialysis. In four years of non-prescription use of naproxen, there have been 26 cases of kidney failure, including three deaths and four patients requiring dialysis.

The Proposed Rule indicates that such a warning was recommended in a position paper published by the National Kidney Foundation 1996. In fact, NKF has advocated such a label change since 1984. We believe that the proposed action by the FDA is scientifically warranted and will serve the interests of the American consumer.

Sincerely,



John Davis, CEO
National Kidney Foundation, Inc.

77N-094I

CZ