

# National Kidney Foundation

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May 18, 2007

Division of Dockets Management (HFA-305)  
 Food and Drug Administration  
 5630 Fishers Lane - Room 1061  
 Rockville, MD 20852

Dear Sir or Madam:

RE: Docket No. 1977N-0094L (Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-The Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling)

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As President of the National Kidney Foundation (NKF), and on behalf of its 50,000 members, I am writing to urge that a warning for patients with kidney disease be included on labels for OTC ibuprofen and other NSAIDs, sold for both adult and pediatric use. We do so in response to the Proposed Rule published in the *Federal Register* on December 26, 2006. This kind of warning has been under consideration by the Food and Drug Administration for more than a decade, and was recommended by the FDA Nonprescription Drugs Advisory Committee at its meeting on September 20, 2002.

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In 1984, NKF called upon the agency to rewrite the package label, bottle label, package inserts, and promotional information for OTC ibuprofen to read: "DO NOT TAKE THIS PRODUCT WITHOUT PHYSICIAN SUPERVISION IF... (4) You have heart disease, high blood pressure, kidney disease, or liver disease." "Statement on the Release of Ibuprofen as an Over-the-Counter Medicine," *American Journal of Kidney Diseases*, Vol VI, No. 1, July 1985. NKF subsequently sponsored a consensus conference on Analgesics and the Kidney, (June 9-11, 1995). The recommendations from that meeting were published in the *American Journal of Kidney Diseases*, Vol 27, No 1 (January 1996), pp 162-165 and were referenced in the Proposed Rule published on December 26, 2006. At that time the NKF recommended "[t]here should be an explicit label warning people taking over-the-counter NSAIDs of the potential renal risks of consuming the drugs."

In the years following the NKF consensus conference a number of studies have been published that provide additional bases for the policy that we

1977N-0094L

21

are recommending. These include: K Gooch, et al., "NSAID Use and Progression of Chronic Kidney Disease," *American Journal of Medicine*. 2007 Mar; 120(3): 280.e1-7. C. Huerta, et al. "Non-Steroidal Anti-Inflammatory Drugs and Risk of ARF in the General Population," *American Journal of Kidney Diseases*. 2005 Mar; 45(3):531-9.

In the *Federal Register* of August 21, 2002 (67 FR 54139), FDA proposed to include ibuprofen in the monograph for OTC IAAA drug products with additional warnings:

"Ask a doctor before use if you have:

Problems or serious side effects from taking pain  
relievers or fever reducers

Stomach problems that last or come back, such as  
heartburn, upset stomach, or pain

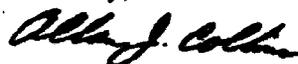
Ulcers

Bleeding problems

High blood pressure, heart or kidney disease, are taking a  
diuretic, or are over 65 years of age."

We respectfully recommend that the agency finalize a label change along these lines as soon as possible. Thank your for your consideration of this request.

Sincerely,



Allan J. Collins, MD  
President  
National Kidney Foundation, Inc.