

#821

Public Citizen

March 9, 1982

Mark Novitch, M.D.
Associate Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Novitch:

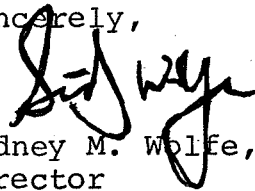
The purpose of this letter is to petition you in writing, as I previously did in a phone conversation on February 10 of this year, to immediately change the labelling on all aspirin-containing products to warn against use by children with chicken pox or during the winter because of the link between aspirin and Reye's Syndrome.

Enclosed is a copy of a report I wrote on February 11th on this subject, containing statements about the need for FDA to put a warning on aspirin-containing products. This February 11th statement has been in the possession of FDA for at least 2-3 weeks.

It is now almost 4 months since the November 12th letter from the CDC Advisory Committee Chairman Dr. R. Alexander to CDC which warned that for children, "the use of salicylates should be avoided, when possible...." FDA epidemiologist Dr. Franz Rosa attended the early October 1981 workshop which preceded the November 12th CDC Advisory Committee letter to CDC and I assume that as a member of the CDC Advisory Committee, he has kept FDA officials informed of these events over the past 4 months.

I hope that FDA moves quickly to warn the public about this serious, life-threatening connection between aspirin and Reyes Syndrome. If this does not occur within a very short time, we will seriously consider initiating legal action to force FDA to adhere to its statutory responsibility to protect the public health.

Sincerely,



Sidney M. Wolfe, M.D.
Director

cc: Dr. Arthur Hull Hayes

Hearing Clerk