



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 1 2000

Food and Drug Administration  
Rockville MD 20857

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Thomas E. Bryant, M.D., J.D.  
President  
Aspirin Foundation of America, Inc.  
1555 Connecticut Avenue, N.W., Suite 200  
Washington, D.C. 20036-1103

Re: Docket No. 00P-1325/CP1

Dear Dr. Bryant:

This letter responds to your citizen petition dated May 31, 2000. In that petition, you request that the Food and Drug Administration (FDA) take enforcement action against the product known as Tylenol Arthritis Extended Relief. You request specifically that FDA direct the manufacturer of this product, McNeil Consumer Healthcare (McNeil), to revise its labeling by removing false or misleading statements. You also request that FDA require McNeil to modify its advertising for this product. For the reasons discussed below, your petition is granted in part and denied in part.

You state that the name "Tylenol Arthritis Extended Relief" is misleading because the product marketed under this name is approved only for the relief of pain associated with arthritis, not for the treatment of arthritis itself. On July 25, 2000, FDA approved a supplemental new drug application (SNDA) for Tylenol (acetaminophen) Extended Release Caplet, 650 mg. As part of its review of that SNDA, FDA approved revised labeling for the product. The approved name for the product is now Tylenol Arthritis Pain. The approved labeling also contains a clarifying statement on the principal display panel stating that the product is for the temporary relief of minor arthritis pain. As of the date of the SNDA approval letter, all newly produced drug product is to contain approved labeling, including the name Tylenol Arthritis Pain and the clarifying statement. Therefore, this portion of your petition has been granted.

You request that FDA take enforcement action against all advertising for the product known formerly as Tylenol Arthritis Extended Relief. However, the U. S. Federal Trade Commission (FTC) regulates advertising for over-the-counter drugs. We have forwarded a copy of your

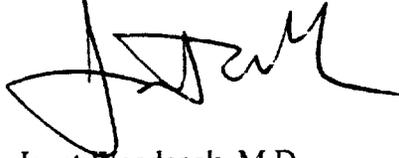
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petition and this response to the FTC. You should contact Anne Maher, 202-326-2987, at the FTC if you believe that any advertising for the Tylenol product remains misleading.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Janet Woodcock', written in a cursive style.

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

cc: Anne Maher  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Suite S8002  
Washington, D.C. 20580