



LIPID NURSE TASK FORCE
MANAGING CARDIOVASCULAR DISEASE

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**Statement of the Preventive Cardiovascular Nurses Association - PCNA
 (Formerly the Lipid Nurse Task Force)**

A representative of the Preventive Cardiovascular Nurses Association would like to have the privilege of reading this position statement regarding Over The Counter Drug Products at the Public Hearings scheduled for June 28-29, 2000. We would respectfully request that our participation be scheduled for Thursday the 29th of June. We greatly appreciate your consideration of this request.

Submitted by:

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To: The Food and Drug Administration, Health and Human Services
Regarding: Over the Counter Drug Products: Public Hearing
Docket No. 00N-1256

To Whom It May Concern:

The Preventive Cardiovascular Nurses Association (PCNA) looks forward to participating in the June 28-29 hearing on "Over-the-Counter Drug Products" and is submitting this letter for inclusion into the public record.

The PCNA is a national membership organization of professional nurses dedicated to the primary and secondary prevention of coronary artery disease, vascular disease and stroke. Our mission is achieved through professional and public education, through increasing consumer awareness of the importance of cardiovascular risk reduction and through advocacy of the need for nursing involvement in the care of persons and families at risk for coronary disease and stroke.

It is estimated that 98 million Americans have blood cholesterol levels of 200 mg/dL and over. This number represents 52% of our adult population. In numerous well designed clinical trials over the past 10 years involving hundreds of thousands of American adults, cholesterol lowering, through the use of HMG CoA Reductase Inhibitors, has been found to be remarkably safe and effective. The results of these trials demonstrated substantial reductions in morbidity as well as mortality. The benefit to quality of life and to the reduction in cost of hospitalizations for coronary disease and stroke is also enormous. These benefits are seen across the adult age span as well as across genders. What is also clear is that millions of Americans with modestly elevated cholesterol are not being identified and/or treated adequately. The need for an effective treatment for elevated cholesterol and the availability of this very safe and effective medication compels us to seriously consider the great public health benefit of allowing this class of medications to be made available over the counter.

We strongly support the concept of OTC availability of an HMG CoA Reductase Inhibitor based upon the satisfaction of the following criteria:

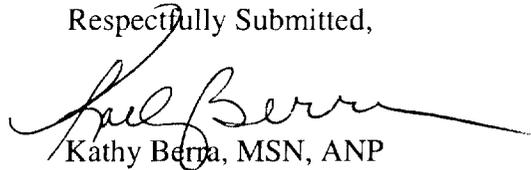
That research demonstrates that the population who chooses to use the product is comprised of appropriate candidates for OTC lipid-lowering therapy, with regard to age, medical history, and baseline lipid levels.

That research shows that those who elect to use the product follow the instructions on the label with regard to dosage and frequency.

That research shows that those who elect to use the product communicate with their health care providers regarding both its use and for clinical follow-up.

The Board of Directors of the PCNA strongly recommend that the FDA consider the benefits of bringing HMG Co A Reductase Inhibitors Over the Counter in order to reduce the burden of Cardiovascular Disease and Stroke that effects 1 in 2 adult Americans.

Respectfully Submitted,



Kathy Berra, MSN, ANP

For the Board of Directors of the Preventive Cardiovascular Nurses Association

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