

Legal Notes

DR. JULIAN M. WHITAKER PETITIONS FDA
TO INCLUDE COENZYME Q10 USE RECOMMENDATION IN ALL STATIN DRUG LABELING

On May 23, 2002, Dr. Julian M. Whitaker filed two citizens petitions with the Food and Drug Administration. The petitions call on the Commissioner of Food and Drugs to change the labeling of all HMG CoA reductase inhibitor drugs (the so-called statin drugs), and to issue a Medication Guide, warning consumers of the need to take coenzyme Q10 (CoQ10) whenever they take a statin drug, as follows:

Warning: HMG CoA reductase inhibitors block the endogenous biosynthesis of an essential cofactor, coenzyme Q10, required for energy production. A deficiency of coenzyme Q10 is associated with impairment of myocardial function, with liver dysfunction and with myopathies (including cardiomyopathy and congestive heart failure). All patients taking HMG CoA reductase inhibitors should therefore be advised to take 100 to 200 mg per day of supplemental coenzyme Q10.

The petitions explain that statins deplete coenzyme Q10 stores in the body and increase congestive heart failure and cardiomyopathy risk. They call on the FDA Commissioner to take immediate action to safeguard the millions of statin drug users.

The petitions explain that statin drug use may be inducing adverse effects in as many as 575,000 statin drug users worldwide. CoQ10 is a substance found within the mitochondrial enzymes; it is an essential source of energy for cells with particularly high metabolic demands, such as the heart muscle. Statin drugs work by blocking cellular production of cholesterol in the mevalonate pathway, but they also block CoQ10 production in that same pathway. Consumption of 100 to 200 mg per day of CoQ10 can reverse CoQ10 depletion induced by statins. Merck has obtained a patent for the combination of CoQ10 with statins in one prescription dose.



Pictured: Dr. Julian M. Whitaker

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