

## FDA ANNOUNCES DECISION ON ANOTHER HEALTH CLAIM FOR DIETARY SUPPLEMENTS

In response to a court decision, FDA is using its enforcement discretion to allow a qualified **health claim, about EPA and DHA omega-3 fatty acids in dietary supplements and reduced risk of coronary heart disease (CHD)**. This claim is being allowed even though the agency had determined that it did not meet the "significant scientific agreement" (SSA) standard that had been previously established for such claims.

The qualified health claim states: *"The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and it is not known whether diets or omega-3 fatty acids in fish may have a possible effect on a reduced risk of CHD. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population."*

Such a claim may be used in labeling for EPA and DHA omega-3 fatty acid-containing dietary supplements, provided that such supplements do not recommend or suggest in the labeling, or under ordinary conditions of use, daily intakes exceeding 2 grams EPA and DHA omega-3 fatty acids.

FDA's decision is reflected in a letter dated and issued October 31, 2000 which outlines modifications FDA has made in its approach in processing this claim and future health claim petitions for dietary supplements. Under this approach FDA intends to exercise enforcement discretion for a qualified health claim for dietary supplements when the following conditions are met:

1. The health claim petition meets FDA requirements for such petitions;
2. The scientific evidence supporting the claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the scientific evidence;
3. Consumer health and safety are not threatened; and
4. The claim meets the general requirements for a health claim.