



Memorandum

Date • April 18, 1997

From Patricia Gee,
FOI Officer, CFSAN, HFS-22

Subject Establishment of Docket 97S-0163, "Courtesy Letters"
from FDA to 30-Day Structure Function Claim Notification
Letters for Dietary Supplements

To Jennie Butler,
Chief, Dockets Management Branch, HFA-305

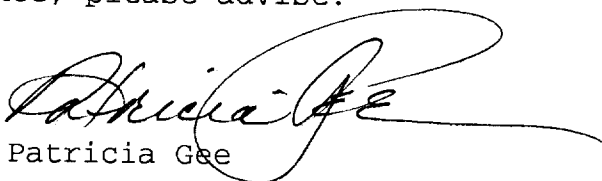
This memo confirms our discussion of April 17, 1997, regarding the establishment of Docket 97S-0163, "Courtesy Letters" (a/k/a "letters of objection") from FDA in response to 30-Day Structure Function Claim Notification Letters for New Dietary Supplements.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) requires that manufacturers notify FDA no later than 30 days after the first marketing of a dietary supplement product bearing nutritional support statement on the label or in its labeling but does not require them to provide FDA with the data that substantiate the claim as defined in **403(r)(6)** of the Act. If however, the claim suggest that the product is intended for other than food use and that the product is subject to regulation under the drug provision of the Act, a courtsey (letter of objection) letter is issued to the manufacturer.

Additionally, in reponse to the new Electronic Freedom of Information Act (EFOIA), these courtesy letters fall under the catagory of "**frequently requested**" documents, which accordingly should be placed in FDA's reading room.

All Courtesy Letters will be sent to you from us.

If I can be of further assistance, please advise.


Patricia Gee

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