



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date April 18, 1997
From Patricia Gee,
FOI Officer, CFSAN, HFS-22
Subject Establishment of Docket 97S-0162, 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-0162, 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.

Additionally, in response to the new Electronic Freedom of Information Act (EFOIA), these 30-Day Structure Function Claim Notification letters fall under the category of "**frequently requested**" documents, which accordingly should be placed in FDA's reading room.

All 30-Day Structure Function Claim Notification Letters will be sent to you from us. There will be no reason for outsiders (manufacturers) to send material to you directly, because if they do, they will have bypassed the notification process.

If I can be of further assistance, please advise.


Patricia Gee

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