



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 18, 1994

Carl Eric Olsen
P.O. Box 4091
Des Moines, IA 50333

Dear Mr. Olsen:

This replies to your letter forwarded to our office on March 31, 1994. You ask how our two dronabinol letters of July 13, 1993, and December 2, 1993, can be reconciled.

Dronabinol in a specific concentration in sesame oil and in a soft gelatin capsule was approved for marketing after the manufacturer submitted to us, as required by law, substantial scientific evidence demonstrating that this drug product is safe and effective for its labeled indications of use. Dronabinol, obtained directly from the marijuana plant, is a raw material and is not approved for any purpose and remains in Schedule I.

Should you have any further questions, please let me know.

Sincerely yours,

A handwritten signature in cursive script that reads "Harold Davis".

Harold Davis
Consumer Safety Officer
CDER Executive Secretariat Staff (HFD-8)
Center for Drug Evaluation and Research