



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington DC 20204

FEB 22 1989

Mr. John C. Fuhr  
Paratherm Corporation  
1050 Colwell Lane  
Building Two  
Conshohocken, PA 19428

Dear Mr. Fuhr:

This replies to your letter of January 25, 1989, concerning the use of Paratherm NF, a mineral oil meeting the specifications of section 172.878, in closed-loop heat transfer systems in food plants.

As stated in our letter of January 18, 1989, we have no objection to the use of this mineral oil in closed-loop heat transfer systems. Since, under the proposed conditions of use, it is not reasonable to expect the mineral oil to become a component of food, the mineral oil would not be considered a food additive as that term is defined under section 201(s) of the Federal Food, Drug, and Cosmetic Act. Therefore, no regulation is required for that use.

While, as requested in your letter, we can state that white mineral oil meeting the specifications of section 172.878 would be considered safe for use in food in accordance with the conditions and limitations imposed by the regulation, the proposed use does not fall within the scope of this regulation, or any other regulation.

In fact, if, as the result of an accident, the mineral oil does become a component of any food being processed, the food may very well be considered adulterated even though it may not necessarily be considered unsafe.

Sincerely yours,

A handwritten signature in cursive script, reading "Pat T. Adamo".

Pat T. Adamo  
Assistant to the Director  
Division of Regulatory Guidance  
Center for Food Safety and  
Applied Nutrition