DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAY 10 1993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

LETTER TO INDUSTRY

Dear Powered Wheelchair Manufacturer:

The Food and Drug Administration (FDA) has received reports of power-driven wheelchairs moving uncontrollably when in the presence of certain radio frequencies. The purpose of this letter is to alert you to this problem.

The FDA has performed Electromagnetic Compatibility (EMC) tests on several brands of power driven wheelchairs. The tests revealed that the wheelchairs are susceptible to interference from radio frequency (RF) and microwave radiation. When the chairs were exposed to common RF radiation, including frequencies emitted from police or fire department radios, the chairs moved uncontrollably. Such EMC-induced brake release and wheelchair movement poses a potential injury risk to the user.

Our tests were designed to examine the radio frequency interference (RFI) susceptibility across a wide band of frequencies, from 1 MHz to 1000 MHz. The chairs tested were found to be susceptible to interference from many different RF and microwave frequencies in which the wheels and brakes of these chairs could be activated by signals occurring over a wide range of frequencies. Consistent wheel movement could be induced with field strengths of about 10 V/m. These levels can be encountered at a distance of more than three (3) feet from a medium power hand-held "walkie-talkie" type radio operating at 450 MHz, such as those used by police and security guards.

Please provide any information that you have concerning this matter such as incident reports, complaints, studies, etc.. We would also appreciate receiving technical information on how this problem, if observed, has been addressed by your firm.

We ask that you respond to this letter within twenty (20) working days of receipt. Your response should include the actions you have taken or plan to take to prevent unintended movement of your powered wheelchairs as a result of radio or microwave interferences.

Please direct your response to Mr. Sterling D. Gary, Division of Compliance Operations, Office of Compliance and Surveillance, Center for Devices and Radiological Health, 1390 Piccard Drive, Rockville, Maryland 20850. If you have any questions, you may contact Mr. Gary on 301/427-1116.

Sincerely yours,

for Ronald M. Johnson
Director
Office of Compliance and
Surveillance
Center for Devices and
Radiological Health