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Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAY 26 1994

. Dear Powered Wheelchair/Scooter or
Accessory/Component Manufacturer:

The information contained in this letter is pertinent to manufacturers of powered wheelchairs, motorized scooters, and related accessories and components.

Technological advancements in the design of powered wheelchairs, coincident with the proliferation of devices that emit electromagnetic (EM) energy (especially communication devices), have caused us to become increasingly concerned about electromagnetic interference (EMI) with powered wheelchairs. We believe that EM energy (or signals) in the environment can pose a potential hazard to users of powered wheelchairs and motorized scooters (collectively termed powered wheelchairs) by causing these devices to move unintentionally. This problem could be exacerbated with the addition of accessories or customizing components to the powered wheelchair.

We have received many reports of erratic, unintentional powered wheelchair movement. There have been instances in which this has resulted in serious injury. It is unclear how many of these incidents have resulted from EMI, but, based on our own field and laboratory tests, as well as information obtained from manufacturers and users of powered wheelchairs, we believe that EMI is one of the causes.^{1,2}

After evaluating this information, we believe that certain steps are necessary to provide information to protect powered wheelchair users from the potential hazards of EMI. These steps, which are outlined more fully below, include:

- the establishment of a minimum recommended immunity level to interfering radiated electromagnetic energy;
- product labeling to warn users of the potential hazards of EMI, provide information about the risks and how to avoid them, and identify the immunity level of the powered wheelchair (if known);
- a recommended educational program to warn users of the potential hazards of EMI and provide information about the risks and how to avoid them; and

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- soliciting of reports of EMI problems and continued monitoring to evaluate the full scope of the problem.

MINIMUM RECOMMENDED IMMUNITY LEVEL

We are now asking that all marketed powered wheelchairs have a minimum immunity level of 20 volts per meter (V/m). Laboratory and field tests by our scientists indicate that this immunity level provides a reasonable degree of protection against the more common sources of EMI. This level is the minimum value proposed by powered wheelchair manufacturers at the ANSI/RESNA meeting in June 1993. It reflects the technological capability that can be immediately implemented by the powered wheelchair industry. We expect that as technology advances, enabling powered wheelchairs to meet higher immunity levels, the 20 V/m recommended level will be increased to provide greater protection to the public.

A testing procedure to determine a powered wheelchair's immunity level is described in the FDA/CDRH Proposed Electromagnetic Compatibility (EMC) Addition to ANSI/RESNA WC/14, Section 36.202.2, entitled **Radiated Radio-frequency Electromagnetic Fields**. We recommend that you use this testing procedure to establish, at a minimum, a 20 V/m immunity level.

LABELING

Because of the evidence of EMI described above, we believe it is necessary to take additional steps to inform powered wheelchair users about the potential for EMI. The goal of this initiative is to inform powered wheelchair users about the risks from EMI associated with the use of powered wheelchairs and how to avoid these risks. Accordingly, we ask that your product labeling on or attached to the powered wheelchair, and the labeling accompanying the powered wheelchair, provide the following information. It should be displayed in a manner that is clear, likely to be understood by the consumer, and not obscured by other information:

1. An explanation of what EMI is, what causes EMI, and the risks associated with EMI;
2. How the user can avoid risks associated with EMI, including warnings to use caution around sources of EMI;

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3. Warnings that the addition of accessories or components, or modifications to a powered wheelchair, may make it more susceptible to EMI, and that there is no easy way to evaluate their effect on the overall immunity of the powered wheelchair;
4. A statement that as of May 1994, 20 V/m is a generally achievable and useful immunity level; and
5. The EMI immunity level of the powered wheelchair, or a statement that the EMI immunity level is not known. Please include a description of the accessories and/or components that were included with the powered wheelchair when tested.

We believe that this information will help minimize the risks associated with unintended movement of powered wheelchairs caused by EMI. We further believe that omission of the requested information would result in a failure of the labeling for the powered wheelchair to include facts material to the consequences of the powered wheelchair's use, and to provide adequate warnings, as required by Section 502 of the Federal Food, Drug, and Cosmetic Act. We request this information be supplied to consumers as soon as it is feasible, and expect that products shipped after December 2, 1994, will be labeled as described above. Accordingly, products shipped after this date without the required labeling may be considered misbranded.

For your convenience, we have attached suggested labeling that you may use as guidance (see ATTACHMENT A).

We are requesting that you send data to support any labeling statements regarding the immunity levels of your products to:

FDA
Document Mail Center
HFZ-401
1390 Piccard Drive
Rockville, MD 20850

Be sure to reference the device's 510(k) document control number. This information must, of course, also be maintained for our review during inspection of your facility. We may conduct field inspections and testing to determine whether your labeling claims concerning the immunity level of your product are accurate.

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EDUCATIONAL PROGRAM

We highly recommend that manufacturers implement an educational program to:

- inform powered wheelchair users and those who care for them about the problems associated with EMI; and
- suggest actions the user can take to minimize those risks.

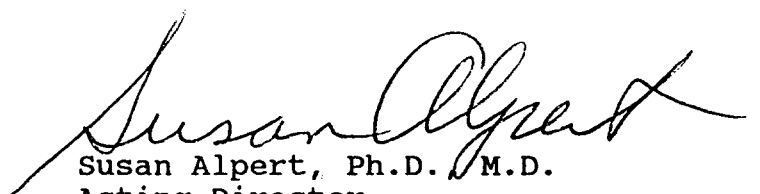
Target populations should include but are not limited to:

- powered wheelchair users;
- senior citizen organizations and centers;
- health care professionals and centers;
- handicapped conveyance providers;
- powered wheelchair distributors;
- medical appliance distributors;
- trade publications that reach powered wheelchair users; and
- health care and advocacy groups that interact with powered wheelchair users.

We will also conduct an educational outreach effort to inform powered wheelchair users about EMI problems and actions they can take to protect against EMI.

We appreciate your prompt attention to this initiative to educate all persons associated with powered wheelchairs of the risks related to EMI and the steps that should be taken to minimize these risks.

If you have any questions concerning this issue, please contact Ms. Marie A. Schroeder, MS, PT, Chief, Restorative Devices Branch (REDB), at (301) 594-1296.



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Acting Director
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1. CDRH letter to powered wheelchair manufacturers dated May 11, 1993.
2. CDRH "Dear Colleague" letter to user groups dated July 7, 1993.

ATTACHMENT A - Suggested Labeling

ATTACHMENT B - WRITE IT RIGHT

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A T T A C H M E N T A

SUGGESTED WORDING FOR DURABLE LABEL ON THE PRODUCT

The following EMI information should be affixed to the powered wheelchair for reference by the user. It should be contained preferably on a durable label and secured to the powered wheelchair within clear view of the user and should also be included in the product literature (see below). The suggested labeling is:

WARNING: Radio wave sources may affect powered wheelchair control

Radio wave sources, such as radio stations, TV stations, amateur radio (HAM) transmitters, two-way radios, and cellular phones, can affect powered wheelchairs and motorized scooters (in this text, both will be called powered wheelchairs). Following the warnings listed below should reduce the chance of unintended brake release or powered wheelchair movement which could result in serious injury.

- 1) Do not turn ON hand-held personal communication devices, such as citizens band (CB) radios and cellular phones, while the powered wheelchair is turned ON;
- 2) Be aware of nearby transmitters, such as radio or TV stations, and try to avoid coming close to them;
- 3) If unintended movement or brake release occurs, turn the powered wheelchair OFF as soon as it is safe;
- 4) Be aware that adding accessories or components, or modifying the powered wheelchair, may make it more susceptible to interference from radio wave sources (Note: There is no easy way to evaluate their effect on the overall immunity of the powered wheelchair); and
- 5) Report all incidents of unintended movement or brake release to the powered wheelchair manufacturer, and note whether there is a radio wave source nearby.

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Important Information

- 1) 20 volts per meter (V/m) is a generally achievable and useful immunity level against interference from radio wave sources (as of May 1994) (the higher the level, the greater the protection);
- 2) This product has an immunity level of [STATE THE IMMUNITY LEVEL OF THIS POWERED WHEELCHAIR MODEL AND INCLUDE THE CONFIGURATION TESTED IN THE ACCOMPANYING LITERATURE; i.e. SPECIFY THE ACCESSORIES AND/OR COMPONENTS INCLUDED FOR TESTING, OR SPECIFY THAT THEY WERE NOT INCLUDED FOR TESTING IN THE OPERATOR'S MANUAL]; or alternatively state
- 2) The immunity level of this product is not known.

SUGGESTED LABELING FOR INCLUSION IN THE ACCOMPANYING PRODUCT LITERATURE

This portion of the labeling will provide the user with basic information that describes the problems with EMI, known sources of EMI, protective measures either to lessen the possibility of exposure or to minimize the degree of exposure, and suggested action should unexpected or erratic movement occur. The suggested labeling is listed below in bold print as follows:

CAUTION: IT IS VERY IMPORTANT THAT YOU READ THIS INFORMATION REGARDING THE POSSIBLE EFFECTS OF ELECTROMAGNETIC INTERFERENCE ON YOUR POWERED WHEELCHAIR.

Electromagnetic Interference (EMI) From Radio Wave Sources

Powered wheelchairs and motorized scooters (in this text, both will be referred to as powered wheelchairs) may be susceptible to electromagnetic interference (EMI), which is interfering electromagnetic energy (EM) emitted from sources such as radio stations, TV stations, amateur radio (HAM) transmitters, two-way radios, and cellular phones. The interference (from radio wave sources) can cause the powered wheelchair to release its brakes, move by itself, or move in unintended directions. It can also permanently damage the powered wheelchair's control system. The intensity of the interfering EM energy can be measured in volts per meter (V/m). Each powered wheelchair can resist EMI up to a certain intensity. This is called its "immunity level." The higher the immunity level, the greater

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the protection. At this time, current technology is capable of achieving at least a 20 V/m immunity level, which would provide useful protection from the more common sources of radiated EMI. This powered wheelchair model as shipped, with no further modification, has an immunity level of [STATE THE IMMUNITY LEVEL OF THIS POWERED WHEELCHAIR MODEL AND INCLUDE THE CONFIGURATION TESTED IN THE ACCOMPANYING LITERATURE; i.e. SPECIFY THE ACCESSORIES AND/OR COMPONENTS INCLUDED FOR TESTING, OR SPECIFY THAT THEY WERE NOT INCLUDED FOR TESTING IN THE OPERATOR'S MANUAL], or alternatively state The immunity level of this powered wheelchair model is not known.

There are a number of sources of relatively intense electromagnetic fields in the everyday environment. Some of these sources are obvious and easy to avoid. Others are not apparent and exposure is unavoidable. However, we believe that by following the warnings listed below, your risk to EMI will be minimized.

The sources of radiated EMI can be broadly classified into three types:

- 1) Hand-held portable transceivers (transmitters-receivers) with the antenna mounted directly on the transmitting unit. Examples include: citizens band (CB) radios, "walkie talkie," security, fire, and police transceivers, cellular telephones, and other personal communication devices. **NOTE: Some cellular telephones and similar devices transmit signals while they are ON, even when not being used;
- 2) Medium-range mobile transceivers, such as those used in police cars, fire trucks, ambulances, and taxis. These usually have the antenna mounted on the outside of the vehicle; and
- 3) Long-range transmitters and transceivers, such as commercial broadcast transmitters (radio and TV broadcast antenna towers) and amateur (HAM) radios.

NOTE: Other types of hand-held devices, such as cordless phones, laptop computers, AM/FM radios, TV sets, CD players, and cassette players, and small appliances, such as electric shavers and hair dryers, so far as we know, are not likely to cause EMI problems to your powered wheelchair.

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Powered Wheelchair Electromagnetic Interference (EMI)

Because EM energy rapidly becomes more intense as one moves closer to the transmitting antenna (source), the EM fields from hand-held radio wave sources (transceivers) are of special concern. It is possible to unintentionally bring high levels of EM energy very close to the powered wheelchair's control system while using these devices. This can affect powered wheelchair movement and braking. Therefore, the warnings listed below are recommended to prevent possible interference with the control system of the powered wheelchair.

WARNINGS

Electromagnetic interference (EMI) from sources such as radio and TV stations, amateur radio (HAM) transmitters, two-way radios, and cellular phones can affect powered wheelchairs and motorized scooters. Following the warnings listed below should reduce the chance of unintended brake release or powered wheelchair movement which could result in serious injury.

- 1) Do not operate hand-held transceivers (transmitters-receivers), such as citizens band (CB) radios, or turn ON personal communication devices, such as cellular phones, while the powered wheelchair is turned ON;
- 2) Be aware of nearby transmitters, such as radio or TV stations, and try to avoid coming close to them;
- 3) If unintended movement or brake release occurs, turn the powered wheelchair OFF as soon as it is safe;
- 4) Be aware that adding accessories or components, or modifying the powered wheelchair, may make it more susceptible to EMI (Note: There is no easy way to evaluate their effect on the overall immunity of the powered wheelchair); and
- 5) Report all incidents of unintended movement or brake release to the powered wheelchair manufacturer, and note whether there is a source of EMI nearby.

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Important Information

- 1) 20 volts per meter (V/m) is a generally achievable and useful immunity level against EMI (as of May 1994) (the higher the level, the greater the protection);
- 2) This product has an immunity level of [STATE THE IMMUNITY LEVEL OF THIS POWERED WHEELCHAIR MODEL AND INCLUDE THE CONFIGURATION TESTED IN THE ACCOMPANYING LITERATURE; i.e. SPECIFY THE ACCESSORIES AND/OR COMPONENTS INCLUDED FOR TESTING, OR SPECIFY THAT THEY WERE NOT INCLUDED FOR TESTING IN THE OPERATOR'S MANUAL]; or alternatively state
- 2) The immunity level of this product is not known.