



Direct Dial: 202.293.8123
jcannon@williamsmullen.com

January 19, 2006

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Attention: George W. Kraus
Consumer Safety Officer
Electronic Products Branch
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health

Gentlemen:

Re: Request for Variance with Respect to the TIA Wavejet Standard

On behalf of TIA Products, a Division of The Richards Corporation, we hereby request a variance from the regulations of the Food and Drug Administration with respect to one model of microwave oven, the Wavejet Standard. As explained below, TIA Products is a small business. Its microwave ovens are manufactured and sold exclusively to aircraft manufacturers for use in aircraft galleys. TIA microwave ovens are not sold to distributors or retailers for use by consumers. TIA therefore requests a variance with respect to the following regulation: The TIA "Wavejet Standard" family does not include a redundant monitor circuit as contemplated by 21 C.F.R. § 1030.10(c)(2)(iv).

Background

TIA Products is a small business with 60 employees in 2005. TIA's 2005 sales of microwave ovens totaled less than 400 units and \$3 million. TIA sells microwave ovens exclusively to aircraft manufacturers for use in aircraft galleys. TIA also sells convection ovens, coffee brewers, and refrigeration units for installation in aircraft galleys. TIA works directly with its customers and various models reflect "custom" modifications to meet the requirements of a particular aircraft galley.

TIA microwave ovens are installed by aircraft manufacturers and modification centers in aircraft galleys. These ovens are not sold through distributors or retailers and are not intended for use by consumers in households. As components designed for and

2006U-0048 *A Professional Corporation* VAR1

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1666 K Street, N.W., Suite 1200 Washington, D.C. 20006 Tel: 202.833.9200 Fax: 804.783.6507 or
202.293.5939 www.williamsmullen.com

installed in aircraft, TIA ovens are subject to all of the testing and inspection requirements of the Federal Aviation Administration (FAA). TIA ovens meet all applicable FAA standards.

Because of the stringent inspection requirements of the FAA, the ovens are maintained only in certified repair shops and by certified mechanics. All installation and removal is performed by qualified mechanics. All work performed on the ovens must be in strict accord with the specifications provided by the manufacturer. The ovens are operated by professionals, members of the flight or cabin crew. This unique application is therefore quite different from the typical household application.

All TIA ovens meet the threshold power density standards set forth in section 1030.10(c)(1) of the regulations. Moreover, all TIA ovens have at least two safety interlocks as required by section 1030.10(c)(2). TIA Wavejet Standard model ovens only lack the monitor circuit contemplated by section 1030.10(c)(2)(vi). These ovens operate on 28 VDC, 115 VAC, 3PH 300-700 HZ, and 115VAC single Phase, 60HZ current. Addition of a monitor circuit would require significant design change and would reduce the level of redundancy found in the current design. We believe that considering the existing interlocks, the design standards and the use environment of the aircraft industry, the Wavejet Standard ovens should not also be required to incorporate a monitor circuit.

Reasons for Waivers

The regulations provide that any of the reporting requirements found in section 1002 may be waived by the Director, Food and Drug Administration pursuant to 21 C.F.R. § 1002.50(a). Section 1010.4 provides that a manufacturer may obtain a variance from the Performance Standards applicable to microwave ovens. First, the variance is requested with respect to a single model oven, the Wavejet Standard, of which there relatively few manufactured each year exclusively for installation in aircraft. Hence, the issue does not warrant an amendment to the standard in the regulation. 21 C.F.R. § 1010.4(a)(1).

Second, the Wavejet Standard meets the criteria for a waiver set forth in 21 C.F.R. § 1010.4(a)(2). The primary and secondary interlocks are illustrated in Attachments 1.7.13 and 1.7.14 to TIA's Product Report. There is also a third interlock, identified as "other" in the Product Report, that separately prevents the circuit from closing or the oven from operating when the door is open. Notably, the regulation requires only two interlocks, backed up by the monitor circuit. 21 C.F.R. §§ 1030(c)(2)(v) and (vi). The Wavejet Standard, however, has an additional interlock. As explained in the Product Report, section 1.7, the "other" interlock is concealed, it is activated by the door opening

mechanism and it actuates before the latch releases the door. As such, the Wavejet Standard "utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard." 21 C.F.R. § 1010.4(a)(2)(i).

In addition, the use of three interlock devices to prevent the oven from operating unless the door is closed is a "suitable means for assuring radiation safety or protection" within the specific operating environment of the Wavejet Standard and the manufacturing cost constraints faced by TIA Production. 21 C.F.R. §§ 1010.4(a)(2)(ii) and (iii). As explained above, TIA Products is a small business producing a limited quantity of custom-made microwave ovens for a unique market: the aircraft galley market. Its customers are manufacturers, not distributors or consumers. The users of TIA ovens are trained personnel, not children. The ovens themselves must meet FAA safety standards and are independently subject to safety inspections on a routine basis. In particular, the redundancy of the interlock switches and the quality and reliability of the components used result in a very high safety level. The controlled environment of the aircraft installation further contributes to the operational safety. Defeating the existing interlocks would require deliberate action inconsistent with the users' training and environment in which the ovens are installed.

Because the Wavejet Standard model ovens have three safety-interlock devices, it would require a deliberate act to defeat simultaneously the interlocks and operate the oven. Not only would a child be unlikely to operate the oven on a commercial aircraft, it would be extremely unlikely that a child would also be able to defeat the interlocks deliberately.

The typical users of microwave ovens on aircraft are not likely even to attempt to override the safety interlocks. The personnel that use aircraft galleys for the preparation of in-flight meals are trained professionals. These personnel must adhere to high standards of safety with respect to numerous actions performed on aircraft. Such personnel are trained to be aware of safety requirements and to respect the correct operating procedures for all of the equipment on the aircraft. Passengers will operate the microwave units occasionally.

In view of the particular environment in which the Wavejet Standard operates, there is no need for what amounts to a fourth layer of redundancy with respect to the safety devices built-in to the Wavejet Standard ovens. At the same time, requiring TIA to retro-fit the Wavejet Standard models is inappropriate and prohibitively expensive. The FAA requires that all galley inserts be securely mounted to the Galley Structure giving operators very limited access to the oven. Removal and re-installation must be performed

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by trained mechanics. Installations must be signed off as complete and the unit functioning properly before flight. Retro-fitting a monitor circuit would therefore require the company to incur substantial costs that are unjustified in the circumstances.

For all of these reasons, the monitor circuit standard should be waived with respect to TIA Products' Wavejet Standard model microwave ovens.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "James R. Cannon, Jr.", written in a cursive style.

James R. Cannon, Jr.
Counsel to The Richards Corporation