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U.S. CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, D.C. 20207

April 30, 1985

OFFICE OF THE
 GENERAL COUNSEL

Mr. James M. Hoff, Business Manager
 Physical Fitness Products
 Diversified Products
 309 Williamson Avenue
 Opelika, Alabama 36803

Dear Mr. Hoff:

This letter responds to your inquiry concerning whether home exercise equipment falls under the jurisdiction of the Consumer Product Safety Commission or the Food and Drug Administration. Under section 3(a)(1) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2052(a)(1), the general definition of "consumer product" subject to the act includes:

... any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; . . .

Home exercise equipment clearly would fall within this general definition. However, "devices" under the Food, Drug, and Cosmetic Act ("FDCA") are specifically excluded from the definition of consumer product by § 3(a)(1)(H) of the CPSA, 15 U.S.C. § 2052(a)(1)(H). Thus, remedies under the CPSA are not available for hazards associated with items of home exercise equipment that are "devices" under the FDCA.

"Device" as defined in the FDCA means "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." 15 U.S.C. § 321(h). The Food and Drug Administration ("FDA") administers the FDCA and has issued regulations that more specifically address the circumstances under which home exercise equipment could be considered devices. 21 C.F.R. Part 890. The regulations make it clear

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that weights, **dumbbells**, straps, adaptive hand mitts, parallel bars, exercise bicycles, treadmills, rowing machines, and the like, whether powered or unpowered, are **devices** within the FDA's jurisdiction when intended for medical purposes, "such as to redevelop **muscles** or restore motion to joints or for use as an adjunct treatment for obesity." 21 C.F.R. §§ 890.5350-5380.

The preamble to FDA's regulation states:

FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances **surrounding** its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them. **Examples** of claims relevant to physical medicine devices that would cause a product to be considered a device include, but are not limited to, claims relating to the following: Re-education, correction, improvement, or maintenance of bodily functions impaired by abnormal bodily states or physiologic functions. Examples of abnormal bodily states or physiologic functions include, but are not limited to, the following: (1) **Neuromuscular** disorders (such as stroke, **muscular** disorders (such as stroke, **muscular** dystrophy, **multiple** sclerosis, and cerebral palsy); (2) **limb** amputations; and (3) **musculoskeletal** disorders (such as arthritis, tendonitis, fractures, and low back pain). FDA has changed the regulations classifying many physical medicine devices to clarify that the regulations apply only to those products intended for medical purposes.

48 Fed. Reg. 53032, 53034-35; November 23, 1983.

Therefore, the Cotmission **must** first decide whether a particular model or class of exercise- equipment is a device intended for medical purposes subject to FDA regulation. This determination can only be made on a case-by-case basis.

Sincerely yours,



Daniel R. Levinson
General Counsel