6b ok
not CPSC Jurisdiction
lab 11/7/83

145

SEP 1 1 1974

Marvin J. Hirn, Esquire
Greenbaum, Doll, Matthews and Boone
3300 First National Tower
Louisville, Kentucky 40202

Dear Mr. Hirn:

This is in further reference to your letter dated June 13, 1974 concerning the Commission's jurisdiction over wheelchairs. By letter dated September 10, 1974 (enclosed), the Assistant General Counsel for the Food and Drug Division of the Department of Health, Education and Welfare advised the Commission that wheelchairs are classified as a "device" under the Federal Food, Drug, and Cosmetic Act (FFDCA). In view of section 3(a)(1)(H) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(1)(H)) which excludes from the Commission's jurisdiction, "devices" as that term is defined in section 201(h) of the FFDCA, it is our conclusion that the Commission does not have jurisdiction to regulate wheelchairs. Rather, jurisdiction over that product lies with the Food and Drug Administration.

Sincerely,

Original signed by
David Schmeltzer
David Schmeltzer
Assistant
General Counsel

Enclosure

AHS
AHSchoem:pm:9/16/74

cc: AHSChoem
GC Chron
GC Reading
GC File

ADVISORY OPINION

145

AHS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD. 20852

OFFICE OF THE
GENERAL COUNSEL

September 10, 1974

Michael A. Brown, Esq.
General Counsel
Consumer Product Safety Commission
Washington, D. C. 20207

Dear Mike:

This is in response to your letter of August 19, 1974, in which you inquire whether the Food and Drug Administration regulates wheelchairs as a "device" under the Federal Food, Drug, and Cosmetic Act.

FDA does classify wheelchairs as a device under the Act. Wheelchairs are included within the device inventory that has already been established, and are presently undergoing classification by the General Hospital and Personal Use Device Classification Panel to determine whether they should be subject to pre-market clearance, standardization, or simple market surveillance.

Sincerely yours,

Peter

Peter Barton Hutt
Assistant General Counsel
Food and Drug Division