



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

D1280B

PHILADELPHIA DISTRICT

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

March 24, 1997

97-PHI-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David W. Ungemach, President
Yeager Wire Works Inc.
620 Broad Street
Berwick, Pennsylvania 18603

GEN.	SPEC.
RELEASE	
F# _____	DATE 3/31/97
Reviewed by: <i>[Signature]</i>	

Dear Mr. Ungemach:

On November 4 and 8, 1996, Food and Drug Administration (FDA) investigator Edward D. McDonald conducted an inspection of your firm located at 620 Broad Street, Berwick, PA, and determined that your firm continues to manufacture and distribute an electrically powered medical lift and recline chair device. This chair is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the above-referenced electrically powered medical lift and recline chair device is adulterated under Section 501(h) of the Act in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to conduct quality assurance audits and failure to have written procedures regarding the performance and documentation of such audits [21 CFR 820.20(b)],

Failure to have a complaint file system [21 CFR 820.198],

Failure to have a Device Master Record (DMR) which contains device, process, packaging, and labeling specifications, and quality assurance procedures and policies, [21 CFR 820.181] and,

Failure to have a Device History Record (DHR) which indicates that a device is manufactured in accordance with the Device Master Record [21 CFR 820.184].

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Our inspection also revealed that you have not yet submitted a 510(k) to the FDA for your electrically powered medical lift and recline chair device. Our previous inspection of November 4, 1994 revealed that your firm has been manufacturing and marketing this product since 1988 without filing a 510(k) with the FDA as required by the Act. As a result, on February 2, 1995 you received a Warning Letter regarding your firm's failure to have an approved 510(k) for your electrically powered medical lift and recline chair. The Warning Letter stated that your electric medical lift and recline chair is adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that it is a Class III medical device under Section 513(f) and is required to have in effect an approved application for pre-market approval pursuant to Section 515(a) or an approved application for investigational medical device exemption under Section 520(g) and no such approval or exemption is in effect. The Warning Letter also stated that your chair is also misbranded within the meaning of Section 502(o) of the Act, in that a premarket notification submission was not provided as required by Section 510(k) of the Act and 21 CFR 807.81.

On February 7, 1995 you responded to the Warning Letter indicating that you would file a 510(k) for your product as quickly as possible. On February 26, 1996 I contacted you by telephone to determine the status of your 510(k) submission. At that time you indicated that you had essentially done nothing short of speaking with Brian Benesch of the Food and Drug Administration's Division of Small Manufacturers Assistance (DSMA). On March 1, 1996 we received a letter from you indicating that you would complete and submit your 510(k) to the FDA within two (2) to three (3) months. To date the FDA has not received a 510(k) submission for your medical lift and recline chair device.

During our November 1996 inspection you indicated to our investigator that Brian Benesch, DSMA, told you that your device was reclassified and no longer required a 510(k). We have contacted Mr. Benesch regarding this and he stated that he did not provide you with any information indicating that your device was exempt. He did, however, provide you with necessary information regarding the submission of a 510(k) for your medical lift and recline chair device.

Additionally, your electrically powered medical lift and recline chair device is misbranded within the meaning of 502(f)(2) of the Act in that its labeling fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe methods of administration

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or application, in such a manner or form, as are necessary for the protection of the users.

The Section 502(f)(2) charge is based on the failure of your device's labeling, including promotional literature, to include the following warning:

Warning:

During a power failure, the chair will remain in whatever position it was in at the time of the power failure. Those persons who cannot exit the chair on their own should have assistance to exit the chair in the event of any such power failure.

Additional warnings may be necessary based on a review of your 510(k), upon receipt.

The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure adherence to each requirement of the Act. You should take prompt action to correct the above-referenced GMP deviations, labeling violation, and submit a 510(k) for your product.

Please advise us of your plans for the product which has been marketed and product presently in your warehouse.

Failure to do this may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please be aware that the reference to "civil penalties" in our February 2, 1995, and March 21, 1997 Warning Letters means that the Food and Drug Administration may assess civil money penalties against you individually and Yeager Wire Works, Inc., for violations of Section 301(a) of the Act, i.e., the introduction or delivery for introduction into interstate commerce of any...device...that is adulterated or misbranded. Your medical lift and recline chair device is adulterated and misbranded under Sections 501(f)(1)(B), 501(h), 502(f)(2), and 501(o) of the Act, as identified in one or both of the referenced Warning Letters covering your medical lift and recline chair device.

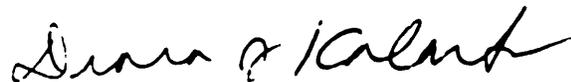
Under Section 303(g)(1)(A) of the Act, FDA may impose civil money penalties of up to \$15,000 on you as an individual, and a like amount on Yeager Wire Works, for each violation of a requirement

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of the Act relating to medical devices, up to \$1,000,000 per respondent for all violations adjudicated in a single proceeding. In each case, a violation of referenced Section 301(a) occurs each and every time you ship a device, e.g., 100 shipments equals 100 violations.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct the above-referenced violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. In view of the results of the most recent inspection and your firm's history, you are requested to attend a meeting in the Philadelphia District Office on April 14, 1997 at 10:00 A.M. to discuss the regulatory status of your firm. If this date and time is not convenient, you may call James C. Illuminati, Compliance Officer at 215-597-4390 x4402 to schedule an alternate time/date.

Sincerely yours,



Diana J. Kolaitis
District Director
Philadelphia District

jci

cc: PA Department of Health
132 Kline Plaza
Suite A
Harrisburg, PA 17104
Attention: Division of Primary Care & Home Health Services
Robert E. Bastian, Director