



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

HFI 35

12/2/97

598

Certified Mail  
Return Receipt Requested

19900 MacArthur Blvd., Ste 300  
Irvine, California 92715-2445  
Telephone (714) 798-7600

**WARNING LETTER**

November 28, 1997

WL-6-8

John F. Wells  
President/CEO  
Wells Johnson Co.  
8000 South Kolb Road  
Tucson, AZ 85706

Dear Mr. Wells:

During an inspection of your firm conducted between October 29 to November 17, 1997, our investigator determined that your firm manufactures a wide variety of general and plastic surgery instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, or servicing are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation as prescribed by Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to establish and control procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria [21 CFR 820.80(d)]. For example, there is no documentation describing the testing performed or the acceptance activities required for the distribution of your oculo-plethysmograph devices.
2. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned functions [21 CFR 820.25(b)]. For example, there are no written procedures or documentation describing any training activities provided to your employees regarding their assigned functions or the requirements of your quality system procedures.
3. Failure to establish and control procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198]. For example, there is no documentation describing the rationale for not performing investigations or the results of

investigations of complaints. Additionally, oral complaints are not documented upon receipt.

4. Failure to ensure that device master records clearly define all the necessary requirements for the manufacture and other particular activities associated with the production of specific devices [21 CFR 820.181]. For example, there are no assembly instructions or other significant quality systems procedures associated with the production of your external ultrasound aspirator.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted a written response to our office concerning our investigator's observations noted on the form FDA 483. Your letter indicates that your office will provide an additional response describing the corrective measures and timetables that your firm has established to make the necessary corrections. Your current response will be made a permanent part of our files.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates To Foreign Governments for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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, injunctions, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action

cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to:

Dannie E. Rowland, Compliance Officer  
U.S. Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612-2445

Sincerely,



Elaine C. Messa  
District Director