



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug AdministrationSan Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6710**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Our ref: 29-51559

May 8, 1997

Debra J. Shaw, President
The Natural Choice Company, Inc.
1155 Chess Drive, Suite #105
Foster City, California 94404**WARNING LETTER**

Dear Ms. Shaw:

We are writing to you because between February 19, 1997 and March 11, 1997, Debra L. Frost, an investigator from the San Francisco District of the Food and Drug Administration (FDA), conducted an inspection of your firm and determined that you manufacture and market a product known as "Double-Up Breast Pump Kit". During the inspection, information was collected which revealed a serious regulatory problem involving this kit.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), the Double-Up Breast Pump Kit is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records show that your firm did not obtain marketing clearance from FDA before it began offering your product for sale. Between December 2, 1996 and February 19, 1997, your firm manufactured and distributed at least [REDACTED] Double-Up Breast Pump Kits without clearance from FDA.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is misbranded under section 502(o) of the

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Act because you did not submit the information necessary to show your device is substantially equivalent to other devices that are legally marketed.

The inspection also revealed that the Double-Up Breast Pump Kits are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice for Medical Devices Regulation (GMP), as set forth in Title 21, Code of Federal Regulations (CFR) Part 820, as follows:

1. You have not documented finished product testing results for the Double-Up Breast Pump Kits released for distribution to ensure that acceptable device specifications were met. (21 CFR 820.184) In addition, there are no written procedures for finished device inspection for these devices (21 CFR 820.160).
2. You have not made a written record of the investigation into the failure of a device after its distribution. From January 15, 1997 through February 18, 1997, eleven out of fifteen complaints received for the Double-Up Breast Pump Kit indicate that the vacuum was low. There is no written failure investigation report for these complaints. (21 CFR 820.162)
3. You have not evaluated and maintained all written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device. For example, a designated individual has not reviewed, evaluated, or maintained written and/or oral complaints received for Double-Up Breast Pump Kits that were returned from retail stores (21 CFR 820.198).
4. There are no written procedures for component acceptance and rejection. For example, you made a decision to replace the adapter caps with replacement components such as black corks which were used in [REDACTED] kits. These corks are milk contact surfaces, and this component change was made without acceptance criteria and without consideration of whether the new corks could result in the finished device being unfit for its intended use. (21 CFR 820.80)
5. Written manufacturing processing procedures for the manufacture of pump motor components and assembly of Double-Up Breast Pump Kits have not been approved. You have also failed to establish and implement formal change control procedures for 1) specification changes to assure that the design basis for the device, components, and packaging is correctly translated into approved specifications, and 2) changes in the manufacturing process of the device (21 CFR 820.100).

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6. Your Device Master Record, dated November 4, 1996, for the Double-Up Breast Pump Kit does not include information required under 21 CFR 820.181. Also, the standard operating procedures in the Device Master Record are not accessible to employees, nor have they been implemented by top management as required.
7. Device History Records for the Double-Up Breast Pump Kits distributed by your firm (including reprocessed units) do not contain information required under 21 CFR 820.184.
8. There is no record of calibration for the pressure/vacuum gauge which is used for finished product testing of the Double-Up Breast Pump Kits (21 CFR 820.61).
9. You have not assured that reprocessed Double-Up Breast Pump Kits are able to meet approved specifications prior to release for distribution. In addition, your reprocessing procedure (memorandum dated December 2, 1996) for this kit does not address information such as: 1) procedures to ensure that the components are adequately cleaned/sanitized as originally specified; 2) a listing of components that may and may not be reused; 3) acceptance/ rejection criteria and specifications for components that may be reused; and 4) original finished product specifications (21 CFR 820.115).
10. Your firm's Quality Assurance Program does not conform to the requirements of 21 CFR 820.20.

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 FDA-483 issued at the close 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 violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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 requests for "Certificates For Products For Export" will be approved until the violations related to the subject devices have been corrected.

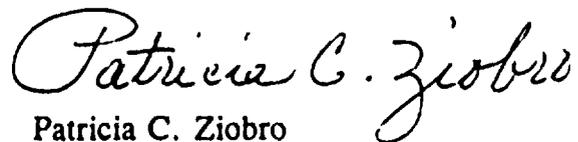
You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

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It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. Please direct your response to: Andrea Scott, Compliance Officer, U.S. Food and Drug Administration, 96 North Third St., Suite 325, San Jose, California 95112.

You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov>.

Sincerely,



Patricia C. Ziobro
District Director
Francisco District