



DEPARTMENT OF HEALTH & HUMAN SERVICES

122278n
Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

December 8, 1998

Ref: 99-DAL-WL-4

WARNING LETTER

VIA FACSIMILE
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert F. Guerney
Corporate Executive Officer
Culpepper Plastic Corporation
P.O. Box 297
Clinton, Arkansas 72031

Dear Mr. Guerney:

During inspections of your firm conducted on June 16 and July 10, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems in the products manufactured and marketed by your firm and labeled as:

- "Medic Mates Acupressure Anti Menstrual Pain Band"
- "Medic Mates Acupressure Sleep Aid Bands"
- "Medic Mates Acupressure Anti Headache Band"
- "Medic Mates Acupressure Anti Sickness Band".

Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The Act requires that manufacturers of medical devices obtain marketing clearance from the FDA for their products 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 do not show that your firm is registered as a medical device manufacturer and that you have listed your devices with the FDA.

Because you do not have marketing clearances from the FDA nor have the products been evaluated for their substantially equivalent status, marketing of your products is a violation of the Act. The products are adulterated under Section 501(f)(1)(B) of the Act in that they are

Page 2 - Mr. Guerney, CEO
Culpepper Plastic Corporation
December 8, 1998

Class III devices under Section 513(f) and they do not have approved applications for premarket approval (PMA) in accordance with Section 515(a) or approved applications for investigational device exemptions (IDE) under 520(g). Your devices are also misbranded within the meaning of section 502(o) of the Act in that a notice or other information with respect to the devices was not provided to the FDA as required by Section 510(k). They are not listed as required by Section 510(j), and they were not manufactured in a facility duly registered in accordance with Section 510.

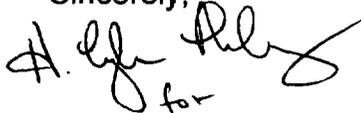
Be advised this serious violation of the law may result in the FDA taking regulatory action without further notice. These actions may include, but may not be limited to seizure, injunction, or civil money penalties. Federal agencies are informed about the warning letters issued by the FDA, so they may consider this information when awarding government contracts.

It is necessary for you to take immediate action on this matter and bring the devices into compliance for further marketing of these products. Please advise this office in writing within fifteen (15) working days from the date you received this letter, of the steps you are taking to effect correction. Please explain how you plan to prevent these violations from happening again. If you need more time to respond, provide an explanation and a time frame when you expect to complete your corrections. Please direct your response to: Mariza Ujaque-Pesante at the above letterhead address.

Finally, you should understand there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issues of premarket clearance for your devices and does not address other obligations you have under the law.

If you have specific questions about how FDA marketing requirements affect your particular device, or about the contents of this letter, please feel free to contact Mariza Ujaque-Pesante at (214) 655-5313 ext. 534.

Sincerely,

A handwritten signature in black ink, appearing to read "A. J. Baca" with a stylized flourish at the end. Below the signature, the word "for" is written in a smaller, simpler font.

Joseph R. Baca
Dallas District Director

Enclosure: Medical Device Registration Package

JRB:MUP:jab

Page 3 - Mr. Guerney, CEO
Culpepper Plastic Corporation
December 8, 1998

cc: Mr. Tony A. Bruckner, President