



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000
FACSIMILE: 303-236-3551

November 5, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

bcc:

Ms. Gacia G. Saenz
President and Co-Owner
C & G Marketing and Manufacturing
243 Little Park Road
Grand Junction, Colorado 81503

Ref. # - DEN-97-03

PURGED

Dear Ms. Saenz:

This letter is in reference to your product, "Soberup" which you distribute and promote as a sobriety aid.

Your firm distributes promotional fliers (labeling) with this product that make numerous claims including, "Before You Saddle Up, Soberup," "Soberup also helps to detoxify alcohol from the system, which can help reduce its effects!" "...the herbs in Soberup have been used in Eastern Medicine for alcohol treatment," "Pueraria Flower...Relieves alcoholic poisoning," "Ginseng...Treats deficiency diseases....," "Polyporous...Diuretic."

These claims for "Soberup," together with the actual name of the product establish that "Soberup" is a drug (Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)) intended for use in minimizing or eliminating the blood levels of alcohol in all categories of individuals who are inebriated (intoxicated, alcohol abuser, alcoholic), while it also claims to treat alcohol poisoning and is intended for use in minimizing or preventing inebriation as a sobriety aid.

"Soberup" is a "new drug" (Section 201(p) of the Act) since there is no evidence that this (or any similar product) is generally recognized as safe and effective for its intended purpose.

"Soberup" may not be marketed in interstate Commerce without approval of a New Drug Application (§505 of the Act).

"Soberup" is also subject to the Final Rule, "Orally Administered Drug Products for Relief of Symptoms Associated with Overindulgence in Alcohol and Food for Over-the-Counter (OTC) Human Use; Decision on Ingredients Intended to Minimize or Prevent Inebriation" (copy enclosed). In that Final Rule, FDA determined that no ingredient is regarded as safe and effective for use in an OTC drug either as a sobriety aid or to minimize or prevent inebriation. Such products may present a potential health hazard, particularly when motorists rely on [unsubstantiated] claims that the products will prevent or minimize the effect of alcohol and reduce an inebriated state. This rule banned all such products as unapproved new drugs and "Soberup" is subject to that prohibition.

In addition, "Soberup" is misbranded (Section 502(f)(1) of the Act) as its labeling fails to bear adequate directions for the uses for which it is offered. The article is also misbranded (Section 502(a) of the Act) in that its labeling is false and misleading, as it suggests that there is substantial evidence to establish that the product is safe and effective for its intended uses, when in fact, this is not the case.

Clinical studies conducted to demonstrate the safety and effectiveness of a "new drug" must be conducted under the requirements of an IND [21 CFR 312 (Code of Federal Regulations)]. The data is then submitted to FDA for scientific review as part of a new drug application. The product may not be marketed until the new drug application is approved by the Agency.

We request that you immediately cease distribution of the product "Soberup" and the related promotional material (labeling).

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that the drug products you distribute are in compliance with the Act and regulations promulgated under the Act. Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

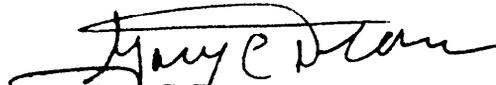
You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

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Your response should be directed to Ms. Shelly L. Maifarth, Compliance Officer, U.S. Food and Drug Administration, P.O. Box 25087, Denver, Colorado 80225-0087. If you have any questions concerning the contents of this letter, please contact Ms. Maifarth at 303-236-3046.

Sincerely,


Gary C. Dean
District Director

Enclosure
Federal Register Notice dated July 19, 1983

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cc: Mr. Edward C. York
Vice President and Co-Owner
C&G Marketing & Manufacturing
243 Little Park Road
Grand Junction, Colorado 81503