



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

December 24, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Bonnie Dassinger
President
B & B Pharmaceuticals, Inc.
17200 East Ohio Drive
Aurora, Colorado 80017

PURGED

Ref. # - DEN-98-04

Dear Ms. Dassinger:

During an inspection of your facility, conducted on August 7 through 13, 1997, by Consumer Safety Officer Elvin R. Smith, it was determined that your firm is repacking drugs for further sale, including Prostaglandin E₁, Morphine Sulfate, Hydromorphone Hydrochloride, Hydrocodone Bitartrate, Fentanyl Citrate, Albuterol Sulfate, Ipratropium Bromide, Cromolyn Sodium, Ketoprofen, Dimercaptosuccinic Acid and Ibuprofen.

Because such labeling includes statements which represent and suggest that these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, these products are drugs within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act "the Act".

During our inspection, we determined that your firm is distributing Prostaglandin E₁, obtained from [redacted] of [redacted]. Marketing of this drug is a violation of the Act as follows:

The article of drug, Prostaglandin E₁, as repacked and relabeled as B & B Pharmaceuticals and distributed for use in preparing human drug products, is misbranded since its labeling is misleading within the meaning of sections 502(a) and 201(n) of the Federal Food, Drug and Cosmetic Act for its failure to reveal a material fact, namely, the information contained within the supplier's labeling for the bulk drug which reads in part "For laboratory research use only. Not for human or veterinary use."

Consumer Safety Officer Smith documented serious deviations from current good manufacturing practice in the repackaging and relabeling of active pharmaceutical ingredients, (APIs). These deviations cause the APIs to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. Section 501(a)(2)(B) of the Act requires that all drugs be manufactured, processed, packed and held in accordance with current good manufacturing practice, (CGMP). The deviations include, but are not limited to, the following:

(1) Your firm has no data demonstrating that the expiration dates it has assigned to repackage APIs are valid. Further, there is no written stability testing program and no stability testing has been performed on repackaged APIs. APIs that your firm repackaged and distributed with expiration dates that are not supported by any stability testing include: Morphine Sulfate, Fentanyl Citrate, Hydromorphone Hydrochloride, Albuterol Sulfate, Ketoprofen, Ibuprofen, Cromolyn Sodium and Dimercaptosuccinic Acid which were distributed with two-year expiration dating; and Cyclobenzaprine Hydrochloride and Ipratropium Bromide which were distributed with five-year expiration dating periods.

(2) Failure to maintain any master production and control records for the repackaging and relabeling of APIs. Your firm lacks written procedures and controls for repackaging and relabeling operations; lacks written specifications for incoming APIs and for repackaged and relabeled APIs; and lacks written specifications for container-closure systems and for labeling. There are no written procedures or criteria for approval or rejection by a quality control unit of incoming bulk APIs, repackaged and relabeled APIs, or labeling and packaging materials.

Your firm received shipments of Prostaglandin that contained warning statements on each vial and on insert labeling that the Prostaglandin is for laboratory research use only and not for human use. Your firm relabeled the vials and distributed the vials to pharmacies. The relabeling did not contain the aforementioned warning statements. When you were questioned by Investigator Smith during the inspection about such labeling practice you informed the investigator that you were not familiar with the warning statements and were not aware that the Prostaglandin is not intended for human use. As noted above, CGMPs require that your firm have appropriate written specifications for the drugs that it repackages and/or relabels and requires that your firm have quality control procedures to ensure conformance with all such specifications.

(3) Failure to maintain adequate batch records in that batch records fail to include specimens or copies of labeling and fail to include identification of the container-closure systems used in repackaging operations. Additionally, the persons performing and directly supervising or checking on repackaging and relabeling operations were not identified in approximately five (5) of 15 batch records reviewed during the inspection. Three of the batch records lacked documentation of a lot number assigned to the repackaged APIs.

(4) There are no written procedures for performing identity testing and there is no documentation showing that identity testing has been performed on each shipment of each batch of bulk API that has been repackaged and relabeled, and distributed by your firm.

The Food and Drug Administration considers these deviations to be serious violations. This list is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of GMPs and the Act.

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Until these violations are corrected, Federal agencies will be informed that the Food and Drug Administration recommends against the award of contracts for the affected products. Additionally, no pending export approval requests will be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action such as seizure and/or injunction without further notice. This letter does not represent a comprehensive review of all the products your firm distributes. It is your responsibility to ensure that all the drug products you distribute are in compliance with the requirements of the Act and regulations promulgated thereunder.

We request that you reply within fifteen (15) working days of your receipt of this letter, stating the specific action(s) you have taken to correct the violations. Your reply should be sent to the Food and Drug Administration, Denver District Office, Building 20 - Denver Federal Center, P.O. Box 25087, Denver, Colorado 80225, Attention: Regina A. Barrell, Compliance Officer.

Sincerely,

A handwritten signature in cursive script, appearing to read "Gary C. Dean for".

Gary C. Dean
Director, Denver District

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