



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-03-23

February 4, 2003

Henry L. Headley, Owner
Icon Laboratories
1644 Ocean Shore Blvd.
Ormond Beach, Florida 32176

Dear Mr. Headley:

During an inspection of your facility at the above address on February 5 and 11, 2002, Investigator Torres determined that your firm manufactures and distributes P-K-5 Pain Relief Medication. The inspection revealed that this over-the-counter (OTC) drug is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMP) regulations for pharmaceuticals (21 CFR, Part 211) as follows:

- a. Failure to perform process validation studies on the manufacturing process of the bulk solution and equipment cleaning processes.
- b. Failure to document, perform, or assure performance of finished product testing on each batch of product manufactured prior to release for distribution.
- c. Failure to test identity and strength of each active ingredient and raw material analyses.
- d. Failure to establish and maintain master production records, batch production records of the manufactured bulk solution, and equipment cleaning and use logs.
- e. Failure to establish an on-going stability testing program in that no stability testing data has been developed.
- f. Failure to list an expiration date on the product or provide adequate stability data supporting that the product is stable for at least 3 years.
- g. Failure to establish procedures for warehousing and distribution of product.
- h. Failure to maintain component, drug product container, closure, and labeling controls or records.
- i. Failure to have written procedures for complaint and product recall handling operations.
- j. Failure of personnel involved in the compounding and supervision operations to have adequate knowledge of CGMP.

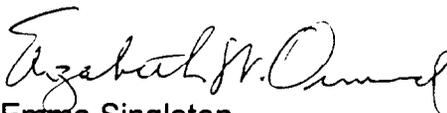
In addition, the P-K-5 label, insert, and carton bear a disclaimer that: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." This disclaimer may only be

used for dietary supplements as provided for under Section 403(r)(6)(C). It is not allowed on topical drug products like P-K-5.

This letter is not intended to be an all-inclusive list of the deficiencies in your labeling and manufacturing of this product. It is your responsibility to ensure adherence to each requirement of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned product and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks of your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. We also ask that you explain how you plan to prevent these violations from reoccurring. Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,


for Emma Singleton
District Director
Florida District Office

Enclosure:
Form FDA 483