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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED ^{AK}

March 9, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 20

George C. Walker
President
Panef Corporation
5700 West Douglas Avenue
Milwaukee, Wisconsin 53218

Dear Mr. Walker:

An inspection of your OTC drug manufacturing facility was conducted on January 26-29, 1999, by FDA Investigators John P. Hermann and Jeffrey Bernhardt. The investigation was prompted by a

We are concerned regarding the report that was prepared by interviews with you and your staff have no although it was suggested that it may have been

It has also been reported to us that horseradish extract was substituted for horsetail extract, one of the stated label ingredients in the products.

We are concerned that an adequate internal investigation has not been conducted into this matter. For example, what is the potential for Have you reviewed all formulations for other products developed for you to determine the validity of the active ingredients? Have

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Certified Finished Product Analysis reports been issued by .

Could ingredient substitutions :

The answers to these and other questions may have already been obtained by your firm. We would appreciate assurance from you that steps have been taken to prevent this from happening in the future.

A Warning Letter was sent to your firm by this office on January 17, 1996, citing deviations from the current Good Manufacturing Practice regulations (GMPs). It should be noted that in your response you stated "All components in our facility have now been properly received, inspected and released according to GMP." Adherence to GMPs provides a check on manufacturing errors. Conformance with this GMP would have revealed that the active ingredient in your component was insufficient to provide the strength stated on the label of your Arthoflex products. In addition, regardless of any agreement with its customers, it is the responsibility of the manufacturer to ensure satisfactory results of analysis for potency and identity prior to release of the product.

During this inspection our Investigators documented continuing serious deviations from the current Good Manufacturing Practice regulations, Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211). These deviations, noted and provided to you on the form FDA-483, cause your arthritis creams to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The GMP violations include but are not limited to:

Failure to withhold from use each lot of components until the lot has been sampled, tested and released for use by the quality control unit. At least one test shall be conducted to verify the identity of each component [21 CFR 211.84(d)(1)]. Each component shall be tested for conformity with all appropriate written specifications for purity, strength and quality [21 CFR 211.84(d)(2)].

Failure to maintain an individual inventory record of each component that shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component [21 CFR 211.184(c)].

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Failure to review all drug product production and control records, including packaging and labeling, by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed [21 CFR 211.192(a)].

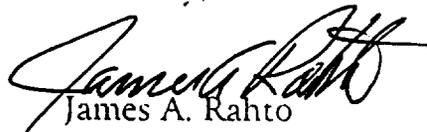
The violations cited in this letter are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the current GMPs.

We have scheduled a meeting with you at our office in Minneapolis, Minnesota, at 1:00 p.m. on Tuesday, March 30, 1999. We will discuss the issues presented in this letter. If you have a conflict with this date and time please notify this office and we will reschedule the appointment.

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. Also, other Federal agencies are informed of the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

We request that you notify this office in writing within 15 working days of your receipt of this letter of the measures you intend to take to correct the cited violations. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Acting Compliance Officer John T. Quaife at the address indicated on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

JTQ/ccl