



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
DETROIT DISTRICT

*Purged by S. Orin 9/25/97*

449

1560 E. Jefferson Avenue  
Detroit, MI 48207-3179  
TELEPHONE: 313-226-6260  
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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER  
97-DT-17

September 22, 1997

Michael Jandernoa  
Chairman of the Board  
Perrigo Co.  
117 Water Street  
Allegan, Michigan 49010

Dear Mr. Jandernoa:

During an inspection of your manufacturing facility located in Montague, Michigan conducted on July 22- August 15, 1997 Investigator Cheryl Fuhs documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

1. Failure of Effervescent Cold Relief and Effervescent Nite Cold to meet all of the active ingredient specifications has not been thoroughly investigated and documented. (21CFR 211.192)
2. Failure to document that employees have been adequately trained to perform their jobs. (21CFR 211.25)
3. Failure to validate the cleaning process for all products. (21CFR 211.67)
4. Failure to document and investigate all complaints. (21CFR 211.198)
5. Failure to conduct annual product evaluations in 1996. [21CFR 211.180(e)]
6. Failure to follow some existing Standard Operating Procedures. (21CFR211.160)

7. Failure to include complete information in the batch record with respect to production problems. (21CFR 211.188)

We acknowledge receipt of your August 25 and 29, 1997 response letters to the FDA 483 issued to your firm on August 15, 1997. We also thank your representatives for coming to Detroit to discuss the inspectional findings during an August 27, 1997 meeting with Compliance Officer Judith A. Putz. The corrections promised in your firm's letters and meeting discussion have been made a part of your file and will be evaluated during the next inspection.

Based on your firm's response, we are concerned that you may be focusing on the narrow issues represented by our observations rather than the larger control issues, which the observations indicate may be present in your operation. There appears to be a pattern of not following existing Standard Operating Procedures. Your systems have identified problems, however, the follow up does not always determine the cause nor seek resolution of the problem. Several of your firm's responses include the creation or revision of Standard Operating Procedures. Your representatives have been cautioned that all of the firm's Standard Operating Procedures should be evaluated not only those cited. Training of your managers as well as production and quality employees is important so that there is a clear understanding of Good Manufacturing Practices (GMP) requirements. Some examples of FDA 483 responses, which demonstrate the need for training and a more comprehensive understanding of GMPs in the August 25 letter from the Corporate Director of Compliance are:

1. Standard Operating Procedure [REDACTED] dated 8/7/97 by North Labs' Quality employees indicates missing information such as initials, times are minor deficiencies in a quality review of a manufacturing card. 21 CFR 211.100 requires documentation at the time a critical step is performed - not before or after.
2. The response to observation #1 lauds the testing system identifying a "few trays" exhibiting high values for Effervescent Tablets. The testing identified a persistent although intermittent problem, which has been allowed to continue and has not been completely investigated.
3. Attachment # 9 dated August 14, 1997 (regarding FD 483 -observation #4) indicates 5 of 108 Effervescent Pain Relief pouches checked of the reserve sample leaked. The North Labs' Compliance employee report does not indicate if the product is within expiration date nor assesses the significance of a 5% failure. The customer's complaint was filed when the product was eight months old. Assuming that the same packaging equipment is in use today and a conscious decision was made to conclude the investigation, why weren't the reserve packages processed on the same equipment both before and after the subject lot checked?

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Perrigo Co.

Montague, MI

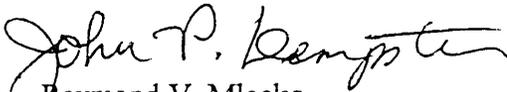
September 22, 1997

The above identification of violations 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 the Good Manufacturing Practice Regulations. Federal agencies are advised on the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office in writing, within 15 working days of your receipt of this letter, of any additional steps you have taken to correct the matters discussed in this letter.

Your reply should be sent to the Food and Drug Administration, Detroit District Office, 1560 East Jefferson Avenue, Detroit, Michigan 48207, Attention: Judith A. Putz, Compliance Officer.

Sincerely,

  
for Raymond V. Mlecko  
Acting District Director  
Detroit District

Enclosure: FDA 483 dtd.0 7/22-08/15/97

cc: George Tilton  
Plant Manager/North Laboratories  
Perrigo Co.  
8060 Whitbeck Rd.  
Montague, MI 49437

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Perrigo Co.

Montague, MI

September 22, 1997

cc: EF - CF 1823985

WL jkt.

GR-RP

Drug Team [GWAP Coordinator - GAD]

PAI Coordinator [MOR]

WL Book

FOI (Gay Dries)

CAF

JAP

HFD-300

HFA-224

HFC-230

HFC-210 CFN 1823985)

RVM:JAP:ljk