



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region **D1056B**

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2906
December 31, 1997

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Mr. Robert Vukovich, Ph.D.
President/Chief Executive Officer
Roberts Pharmaceutical Corp
4 Industrial Way West
Eatontown, New Jersey 07724

RELEASE

REVIEWED BY JRK 1/15/98
CO. DATE

File: 98-NWJ-13

Dear Mr. Vukovich:

During inspections of your firm located at the above address between the dates of November 13 and December 1, 1995, October 28 and November 18, 1996, October 28 and November 14, 1997, and review of your firm's new drug applications on file with the Agency, our investigators documented violations of the new drug provisions, Section 505(a) and 505(k) of the Federal Food, Drug and Cosmetic Act (Act) for various drug products you market. These violations are as follows:

Your firm has no system for maintaining required records and has failed to maintain required records or make required reports in several instances regarding approved new drug applications on file with FDA as evidenced below.

Your firm extended the expiration date of Topicycline (Tetracycline Hydrochloride) Topical solution lots [redacted] and [redacted] to 48 months, an additional 24 months, without submitting and receiving approval of a supplement containing a new revised stability protocol. Your firm extended the expiration date of Furacin 28 gram Soluble Dressing product, containing a new revised stability protocol [21 C.F.R. 314.70(b)(2)(ix)]. Since the lots were marketed with an expiration date outside the conditions of the approved application, these lots were "new" drugs pursuant to Section 201(p) and were marketed in violation of Section 505(a) of the Act.

No annual reports were filed for Topicycline for the periods of September 1, 1994 through August 31, 1995, September 1, 1995 through August 31, 1996, and September 1, 1996 through August 31, 1997. No data was submitted regarding the two Topicycline lots [redacted] and [redacted] marketed with the extended expiration dates that were undergoing stability studies during this time period [21 C.F.R. 314.81(b)(2)].

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Field Alert reports were not submitted for out of specification stability results for Topicycline lots [REDACTED] and [REDACTED] [21 C.F.R.314.81(b)(1)(ii)].

Your firm has failed to supplement Furacin Soluble Dressing NDA 05-795 to include PharmAssist Analytical Laboratory as a new contract laboratory [21 C.F.R.314.70(c)(3)].

No annual reports were filed for Dopar (levodopa) capsules NDA 16-913 for the period of July 30, 1994 through June 30, 1995, July 30, 1995 through June 30, 1996, and July 1, 1996 through June 30, 1997 [21 C.F.R.314.81(b)(2)].

No annual reports were filed for Duvoid tablets ANDAs 86-262, 86-263, and 85-882 for the period of April 1, 1994 through March 31, 1995, April 1, 1995 through March 31, 1996, and April 1, 1996 through March 31, 1997 [21 C.F.R.314.81(b)(2)].

No annual reports were filed for Norethin 1/35E-21 NDA 71-480, 1/35E-28 NDA 71-481, 1/50M-21 NDA 71-539, 1/50M-28 NDA 71-540 for the period of April 1, 1994 through March 31, 1995, April 1, 1995 through March 31, 1996, and April 1, 1996 through March 31, 1997 [C.F.R.314.81(b)(2)].

The content of the approved supplements for Ethmozine NDA 19-753 S-002, S-003, S-004, and S-005 could not be determined from the documentation available at your firm. It is your responsibility to assure you have received a complete copy of the applications including supplements, or to request a copy from FDA's files [21 C.F.R.314.72(a)(2)(iii)].

This letter does not represent a comprehensive review of all the products your firm distributes. It is your responsibility to assure that all requirements of the Federal Food Drug and Cosmetic Act and regulations promulgated thereunder are being met.

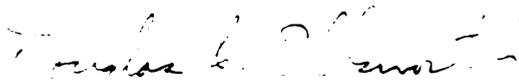
We are in receipt of your written responses dated December 5 and 8, 1997 to the FDA483 List of Inspectional Observations. We have reviewed your responses and statements of corrective action plans, which will be verified during a future inspection at your firm.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific 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 the corrective action cannot be completed within 15 working days, state the reason for the delay and the time needed to complete the corrections.

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Please submit your response to the Food and Drug Administration,
New Jersey District Office, 10 Waterview Blvd., 3rd Floor,
Parsippany, NJ 07054, Attention: Joy R. Kozlowski, Acting
Compliance Officer.

Sincerely,



DOUGLAS I. ELLSWORTH
District Director
New Jersey District

JRK:sw

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Distribution:

bcc: HFR-MA340 (DCB/JRK/JKT/WL File)
HFR-MA350 (DIB/Gp 6-Monitor/Gp 6-Slobotsky/Dellafave)
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w/exhibits

HFA-224
HFC-240 (MPQAS)
HFC-210 (Division of Compliance Policy)
HFI-35 (FOI - stamped and purged copy)
EF (Roberts Pharmaceutical Corp, Eatontown, NJ)

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