



May 26, 2004

VIA FEDERAL EXPRESS

William S. Propst, Sr.
President/CEO
Vintage Pharmaceuticals, Inc.
1236 Jordan Road
Huntsville, Alabama 35811

WARNING LETTER
(04-ATL-10)

Dear Mr. Propst:

An inspection of your drug manufacturing facility located at 3241 Woodpark Boulevard in Charlotte, North Carolina 28206, was conducted by Food and Drug Administration investigators between March 29 and April 2, 2004. One of the purposes of that inspection was to determine your firm's compliance with the Postmarketing Adverse Drug Experience (PADE) reporting requirements of Section 505(k) of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations (21 CFR), Part 314.80.

Section 505(k)(1) requires an applicant to establish and maintain records, and report data relating to clinical experience and other data or information for drugs for which an approval of an application filed under 505(j) is in effect. Our inspection revealed that your firm violated Section 301(e) of the Act because it failed to comply with 21 CFR 314.80 and Section 505(k)(1).

Our inspection revealed significant deviations from 21 CFR 314.80 to include:

1. You have failed to submit quarterly periodic adverse drug experience reports within thirty days of the close of the quarter. These ADEs should be reported at quarterly intervals for the first three years from the date of approval of the application as required by 21 CFR 314.80(c)(2). According to records provided by your firm this would have included [REDACTED] drug products listed under [REDACTED] different ANDA numbers. In fact, your firm has submitted no quarterly reports for any product covered by such an application.

2. You have failed to submit annual periodic ADE reports within 60 days of the anniversary date of the approval of the application as required by 21 CFR 314.80(c)(2). According to your firm's records this failure encompassed [REDACTED] drug products listed under [REDACTED] different ANDA numbers. Your firm has submitted no annual reports for any product covered by such an application.
3. You have failed to develop adequate written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA, as required by 21 CFR 314.80(b). You have established no procedures for the prompt review and identification of all adverse drug experience information obtained. This information includes information obtained or otherwise received from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigation, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

Our inspection revealed that your firm had never submitted an ADE to FDA. This would include any 15 day alert, quarterly report or annual report for any application. The reports are handled as all other incoming complaints. Your complaint procedure does not address the identification and handling of ADE reports. A cursory review of the complaint log by our investigators found several experiences which should have been reported under the ADE requirements. Although individuals at your firm have been identified as being responsible for handling ADE reports, they have received no training in this area of the regulations. Your firm has made no efforts to comply with the regulations that govern the postmarketing reporting of adverse drug experiences.

The above is not intended as an all-inclusive list of violations. At the conclusion of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with [REDACTED] Plant Manager. A copy of the FDA 483 is provided for your review. It is your responsibility to ensure adherence to each requirement of the Act and its regulations. The FDA expects drug manufacturers to establish reasonable mechanisms to assure that all adverse drug experiences are recorded, evaluated, and submitted to the FDA within established timeframes as required under 21 CFR 314.80.

You should take prompt action to correct these deviations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure or injunction. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the deviations and prevent their recurrence. If corrective action cannot be completed within thirty (30) working days, state the reason for the delay and the date by which the

corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. We recommend that you submit a letter to the FDA for each application with an overdue periodic report. This letter should outline the reason for the delay in submitting these periodic reports and the steps you plan to take to insure that these periodic reports, and the next regularly scheduled periodic reports for these applications, will be submitted to the FDA in a timely manner.

We acknowledge receipt of a response to the inspectional observations from Jeffrey Green dated April 29, 2004. The response addressed some but not all of the deficiencies noted. Although new ADE reporting procedures were submitted, your firm's response to FDA 483 observations #1 and #2 fails to identify data in your customer complaint files as adverse event data. This may indicate that your firm did not adequately implement the new procedures or that they are deficient. Your reply should be sent to the Food and Drug Administration at the above letterhead address to the attention of Philip S. Campbell, Compliance Officer.

Sincerely,



 Mary Woleske, Director
Atlanta District

cc: Jeffrey L. Green, Plant Manager
Vintage Pharmaceuticals Inc.
3241 Woodpark Boulevard
Charlotte, North Carolina 28206

Enclosure