ANDA 74-843/S-001, S-002, S-003, and S-005

February 15, 2001

Vintage Pharmaceuticals, Inc.
Attention: Christopher J. Nascone
3241 Woodpark Blvd.
Charlotte, NC 28206

Dear Sir:

This is in reference to your supplemental abbreviated new drug applications dated February 26, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), regarding your abbreviated new application for Propoxyphene Napsylate and Acetaminophen Tablets USP, 100 mg/650 mg.

Reference is also made to your amendments dated August 25, 2000.

These supplemental applications, submitted as "Prior Approval Supplements" according to section 506A(c) of the Act, provide for the following changes:

S-001: The addition of an additional strength: Propoxyphene Napsylate and Acetaminophen Tablets USP, 50 mg/325 mg;

S-002: the addition of 10-count bottle and blister package of the new 50 mg/325 mg tablet strength;

S-003: updated labeling to provide the above changes; and

S-005: an alternate supplier of the raw material acetaminophen, [ ].

We have completed the review of these supplemental abbreviated applications and have concluded that drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are

approved. The Division of Bioequivalence has determined your Propoxyphene Napsylate and Acetaminophen Tablets USP, 50 mg/325 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Darvocet-N 50® Tablets, 50 mg/325 mg, of Eli Lilly and Co.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

We remind you that you must comply with the requirements for an approved abbreviated application described in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any changes in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research