Pamlab, L.L.C.

Quality Pharmaceuticals Since 1957

P.O. Box 8950
Mandeville, LA 70470
(985) 893-4097
FAX (985) 893-6195

December 5 , 2003

2563 '03 DEC -5 A10:02

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

COMMENT: Docket No. 2003D-0478
Guidance: Marketed Unapproved Drugs — Compliance Policy Guide
68 Federal Register 60702, October 23, 2003

Dear Sir or Madam:

Pamlab, L.L.C. ("Pamlab"), is a pharmaceutical company based in Covington, Louisiana, near New Orleans. Founded in 1957 as Pan American Labs, our company develops, licenses, and markets drugs for a select medical specialties, including the treatment of allergies. We have representatives in over 100 markets throughout the United States. We appreciate the opportunity to comment on the FDA's draft Compliance Policy Guide ("Draft Guide") regarding the marketing of unapproved drugs, which was announced in a Federal Register notice on October 23, 2003.

We applaud the Agency's intention, as set forth in the Draft Guide, to give high priority to enforcement actions regarding unapproved drug products. We agree that targeting drugs that challenge the drug approval system helps to preserve its integrity. In particular, we urge the Agency to pursue vigorously and swiftly one of its stated enforcement targets: "drugs that directly compete with an approved drug, such as when a company obtains approval of an NDA for a product that other companies are marketing without approval" (Draft Guide, page 3).

Pamlab currently faces precisely this type of predicament. We have developed two new prescription antihistamine products: (1) Palgic Carbinoxamine Maleate Tablets USP 4mg and (2) Palgic Carbinoxamine Maleate Oral Solution 4mg/5ml. Through our contract manufacturer Mikart, Inc., Pamlab has obtained the required FDA marketing approvals for its new carbinoxamine maleate products.[1] *See* ANDA #40-442 (Carbinoxamine Maleate Tablets USP 4mg); ANDA #40-458 (Carbinoxamine Maleate Oral Solution 4mg/5ml). Only after Pamlab secured FDA approval did we launch these products, to coincide with the autumn 2003 allergy season.

[1] Carbinoxamine maleate products were originally marketed under two new drug applications (NDAs) obtained in 1953. One NDA was approved for carbinoxamine maleate tablets (4mg and 8mg). The other NDA covered a carbinoxamine maleate elixir of 4mg/5cc. When these two NDAs received Drug Efficacy Study Implementation (DESI) review, FDA made an initial determination of effectiveness and confirmed their status as "new drugs." *See* 36 Fed. Reg. 9339 (May 22, 1971). Pamlab's carbinoxamine maleate products contain the same active ingredient as the earlier products originally approved under the 1953 NDAs. Pamlab therefore could not market its carbinoxamine maleate products without an approved ANDA. Mikart has obtained the required ANDA approvals, so now Pamlab's Palgic products can be legally marketed.

2003D-0478 C7

Pamlab is aware, however, of at least nine companies that are currently marketing similar single-ingredient carbinoxamine maleate products without having first obtained marketing approval from FDA.[2] Some of these products contain extended release formulations and claims that are also unapproved by FDA. Through our attorney, Pamlab has served written notice to these companies that they are in violation of the FDCA. As we have stated in previous communications with FDA, we urge FDA to have these unapproved products immediately removed from the market. Because these products continue to be held out to the public as legally marketed products by wholesalers and companies such as FirstDataBank, which lists allegedly therapeutic products and is widely relied on by pharmacists and drug stores, at a minimum, FDA should individually notify these nine companies directly that such marketing violates federal law.

In taking enforcement action against unapproved guaifenesin, FDA stated that other companies marketing unapproved products "should not . . . expect any grace period to protect them from the necessity of leaving the market for some period of time while obtaining approval." *See* FDA Talk Paper, *FDA Issues Letter Discussing Its Enforcement Policy for Unapproved Drugs* (February 26, 2003), at 2. The basis for FDA enforcement action against unapproved carbinoxamine maleate products is even stronger than for guaifenesin. Because the guaifenesin products were non-DESI, no "new drug" determination was made until 2002. Single-ingredient carbinoxamine maleate products, however, were determined to be "new drugs" during the DESI process in 1971. For over 32 years, therefore, the need to obtain marketing approval for these products has been clear.

The marketing of the unapproved carbinoxamine maleate products by these nine companies violates the FDCA and undermines the incentives for companies to invest in obtaining proper FDA approvals for such products. It calls for immediate enforcement action under current FDA policy and this Draft Guide. We urge FDA to do so without delay.

Sincerely yours,

Samuel M. Camp
Chairman and Chief Executive Officer

---

[2] The nine companies of which Mikart is aware are Great Southern Laboratories; Teamm Pharmaceuticals Inc.; Scientific Laboratories Inc.; Brekenridge Inc.; PFAB LP d/b/a Pharmafab; Elge Inc.; Zyber Pharmaceutical Inc.; Pharmaceutical Assoc. Inc., Div. Beach Products; and Atley Pharmaceuticals Inc. As noted in the attachment, some of these companies are marketing carbinoxamine maleate products in more than one size or dosage form.