

Pamlab, L.L.C.

Quality Pharmaceuticals Since 1957



June 12, 2006

Dear Pamlab Customer:

We are writing to call your attention to the two specific actions taken by the FDA regarding:

- a) issuance of a final guidance document outlining how they will address the marketing of medicines that are unapproved by the FDA, and
- b) specific enforcement action to stop the manufacturing of unapproved carbinoxamine and carbinoxamine-containing products which are unapproved.

FDA has ordered all manufacturers to cease the manufacture of unapproved carbinoxamine-containing products within the next 30-90 days. This affects 26 manufacturers and a total of 120 prescription drug products.

To quote Dr. Steven Galson, the Director of FDA's Center for Drug Evaluation and Research: "Unapproved drugs may not meet the modern standards for safety, effectiveness, quality, and labeling. Clearly this is a problem we intend to fix. Right now, many unapproved drugs represent a public health threat because consumers wrongly assume that these widely marketed and available drugs are approved and have been found safe and effective by the FDA"

The only FDA approved applications for carbinoxamine are two ANDAs submitted by Mikart, Inc of Atlanta, which are licensed to Pamlab, L.L.C. under the brand name PALGIC®. These are:

PALGIC® 4mg carbinoxamine tablets*

(ANDA 40-442) / NDC # 0525-6748-01 (bottles of 100) / 0525-6748-05 (bottles of 500)

PALGIC® 4mg/5mL carbinoxamine oral solution*

(ANDA 40-458) / NDC # 0525-6752-16

Physicians Total Care is a repackager of Palgic Products.

You may be assured that PALGIC® will remain on the market as of the only FDA approved carbinoxamine products for the foreseeable future.

For your convenience, we have provided the following links and pdfs as references that will offer you more information about this latest announcement.

FDA Announcement to Improve Drug Safety / Manufacture of Unapproved Carbinoxamine Products Must Cease (June 8, 2006)

<http://www.fda.gov/bbs/topics/news/2006/new01384.html>

Questions and Answers about Unapproved Drugs and FDA's Enforcement Action Against Carbinoxamine Products (June 8, 2006)

http://www.fda.gov/cder/drug/unapproved_drugs/qa.pdf

Guidance Document: Marketed Unapproved Drugs - Compliance Policy Guide (June 8, 2006)

<http://www.fda.gov/cder/guidance/6911fn1.pdf>

Please do not hesitate to call if we may be of any further help to you in this matter.

Pamlab, L.L.C.

*Please see attached for full prescribing information.