

# Pamlab, L.L.C.

Quality Pharmaceuticals Since 1957

*Eric M. Wingerter  
President and CEO*



June 9, 2010

Dear Valued Customer:

As a valuable customer of Pamlab, LLC, we want to update you on products currently being substituted in some instances for Pamlab products, including Neurpath-B, a product of Acella Pharmaceuticals. The L-Methylfolate component of Neurpath-B is identified as XOLAFIN-B™.

In my letter of May 19 (attached), we established that XOLAFIN-B™ is manufactured in China. Laboratory testing of this Chinese active ingredient (CAS #151533-22-1), which Acella has apparently trademarked as XOLAFIN-B™, shows at three (3) months accelerated stability (40°C & 75% Relative Humidity), when incorporated into the same formulation used in Metanx®, that it falls out of specification in the first month. (Specification is >100%. Result at one (1) month is 82.6%).

Although Acella labels its Neurpath-B product with 24 months expiration dating, neither Acella nor its contract manufacturer has actually performed stability testing to support this claim.

Since our May 19 letter we have learned additional facts.

On June 23, 2010 Neurpath-B with an expiration date of April 2012 was evaluated by a third party testing laboratory, BioScreen Testing Services of Torrance, CA (a FDA Registered, California State Certified and DEA Registered testing laboratory). The assay results showed the L-Methylfolate Calcium used in Neurpath-B, XOLAFIN-B™ to be out of specification within two months of being manufactured.

BioScreen Testing Services' testing of Acella's Neurpath-B (Lot # 003321) showed the L-Methylfolate Calcium assay for two replicate samples are as follows (for reference: 3 mg is Acella's label claim):

4099 Highway 190  
Covington, LA 70433  
Phone: (985) 893-4097  
Fax: (985) 867-5773

**Replicate-1: 2.03mg/tablet** ( $2.03/3.0 = 67.7\%$  of Acella's label claim); and,

**Replicate-2: 1.71mg/tablet** ( $1.71/3.0 = 57.0\%$  of Acella's label claim).

USP stability assay in the 2010 USP32 / NF27 Compendia Monograph for Water Soluble Vitamins Tablets states a requirement that the assay for these ingredients are not fall below ninety (90%) of label claim during the expiration dating provided on the label by the manufacturer/distributor of the product.

Pamlab believes that the quality of pharmaceuticals is critical to its customers and we want to provide you with this important information. Pamlab deeply values its relationship with you and appreciates your continued interest and support of Pamlab and our products.

If your patients experience reduced clinical benefits or adverse events on a Pamlab product or any of the products linked to a Pamlab product above, please contact Robert Tyburski, Pamlab Regulatory Manager at 985.893.4097.

Sincerely yours,

A handwritten signature in black ink that reads "Eric Wingerter". The signature is written in a cursive, flowing style.

Eric Wingerter  
President and Chief Executive Officer

ATTACHMENTS:

Bioscreen test Report,

May 19, 2010 Pharmacists letter

# Pamlab, L.L.C.

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*Eric M. Wingerter*  
*President and CEO*



May 19, 2010

Dear Valued Customer:

We feel obligated to inform our valued customers of the following information regarding the active ingredient XOLAFIN-B™ (described as L-methylfolate Calcium) in Acella Pharmaceuticals' products:

- **XOLAFIN-B™ May Not Be Used by Chinese Drug Manufacturers:** The ingredient that Acella calls XOLAFIN-B™ comes from a manufacturer in China that is not cGMP certified by either the Chinese or U.S. governments. Chinese law prohibits Chinese pharmaceutical companies from purchasing a drug substance from a manufacturer without a GMP certificate (*See*, the "Drug Administration Law of the People's Republic of China" Articles 9, 11, 34, 48, 68, 74 & 79, and the "Regulations for Implementation of the Drug Administration Law of the People's Republic of China" Articles 5, 6, 7, 9, 10, 63 & 64). Pamlab wants to make consumers and our customers aware of this situation and also assure them that all of the active ingredients in Pamlab's Metafolin® containing products, including Metanx®, are manufactured by U.S. cGMP compliant facilities.
- **XOLAFIN-B™ Stability Issues:** Laboratory testing of this Chinese supplier's active ingredient (CAS #151533-22-1) which Acella has apparently trademarked as XOLAFIN-B™ shows that, at three (3) months accelerated stability (40°C & 75% RH), when incorporated into the same formulation used in Metanx®, it falls out of specification in the first month. (Specification is >100%. Result at one (1) month is 82.6%). Although Acella labels its Neurpath-B product with 24 months expiration dating, neither Acella nor its contract manufacturer has actually performed stability testing to support this claim.
- **XOLAFIN-B™ May Not Be Generally Regarded as Safe (GRAS):** All ingredients used in medical foods must be GRAS or FDA approved food additives per 21 U.S.C. § 321(s). Pamlab has verified GRAS status for all of the active ingredients in its products that compete with the Acella products listed below. This took several years to complete. Pursuant to FDA regulations, Acella is not allowed to reference Pamlab's GRAS designation hence they are required to independently verify GRAS

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status for its products. As long as “Xolafin-B™” is manufactured in a Chinese facility that is not cGMP certified by both the Chinese and U.S. regulatory bodies, it cannot be considered GRAS because the manufacturer of a GRAS compound MUST be cGMP certified in both the country where the ingredient is made and where it is intended to be sold.

- **Acella Products that contain XOLAFIN-B™.**

<b>Order#</b>	<b>Acella Product</b>
42192-0317-90	NEURPATH-B
42192-0312-30	L-METHYLFOLATE CALCIUM 7.5 MG
42192-0313-90	ENFOLAST-N
42192-0316-90	ENFOLAST

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President and Chief Executive Officer