spectrum®
CHEMICAL MFG CORP
Trusted Since 1971

ACKNOWLEDGEMENT & CERTIFICATION:

For Repackers, Relabelers & Distributors

PHENYLPROPANOLAMINE & SALTS

Company: _____ Customer #: _____
Customer Fax: _____ Tel: _____ Attn/Contact Person: _____
Address: _____
City, State, Zip: _____
Date: _____ Spectrum Representative: _____

Dear Customer: The United States Food and Drug Administration has issued a public health advisory concerning Phenylpropanolamine Hydrochloride. Due to its link with increased risk of hemorrhagic stroke in women and the possibility of such increased risk in men, FDA is taking steps to remove Phenylpropanolamine (PPA) from all drug products and has requested that all drug companies discontinue marketing products containing PPA. FDA also recommends that consumers not use any products that contain PPA. FDA's Nonprescription Drugs Advisory Committee determined that there is an association between PPA and hemorrhagic stroke and recommended that PPA not be considered safe for over-the-counter use. FDA has significant concerns because of the seriousness of a stroke and the inability to predict who is at risk. FDA does not consider the conditions for which PPA is used, either over-the-counter or by prescription, as justifying the risk of such a serious event. The FDA's Center for Drug Evaluation and Research has announced that, based on these developments, FDA intends to initiate rulemaking to classify PPA as not generally recognized as safe and effective for OTC use. FDA also has significant concerns about the continued use of PPA in prescription drug products and intends to take action to remove PPA from prescription drug products as well.

All Phenylpropanolamine products supplied by Spectrum are labeled "Not for Human Use." They are supplied subject to the understanding and agreement that such restrictive labeling will not be deleted from any product further distributed and that all necessary measures will be taken to ensure compliance with applicable DEA chemical diversion prevention regulations in 21CFR 1300 *et seq.*

I hereby acknowledge receipt of the above notification and certify that the Phenylpropanolamine products supplied by Spectrum will be used exclusively for veterinary purposes or research, and will not be administered directly or indirectly to humans in any form. I agree to take all necessary measures to ensure that the above controls and restrictions are maintained in force by persons to whom I may further distribute products containing Spectrum-supplied Phenylpropanolamine or its salts.

Intended Use: _____

For (Purchasing Organization): _____

Name and Title: _____

Signature: _____ **Date:** _____

PLEASE FAX COMPLETED FORM TO (310) 516-2014