

## Report Reaction, LLC

On December 22, 2006, Congress passed Public Law 109-462 entitled Dietary Supplement and Non-prescription Drug Consumer Protection Act.

This requires all dietary supplements and OTC drugs sold under a FDA Monograph, to have a way for consumers to report serious adverse reactions to the product. A company receiving such a report must file certain forms with the FDA with 15 days of receipt.

The key issues are that serious is defined by the FDA not the consumer. If there is a serious injury, this could result in litigation. Serious adverse reactions are rare in drugs that also make cosmetic claims. The second issue, besides seeing if the consumer issue is serious or not, is the proper and timely filling of the necessary forms. Report Reaction fills in what can be done and then guides the user on how to complete, sign and send the report to the FDA.

Report Reaction was originally set up to provide a US address for consumers to contact. Foreign manufacturers had a problem establishing such a US address. Many US companies found it easier to outsource this to Report Reaction. The reasons given were the assurance that the information would get to the correct person in sufficient time to comply with this Law. It was one less item to find in the corporate mail box which required immediate attention. Finally it was cost effective and it actually sounded better on the label.

The Law gives the option of a phone number or an address. The use of a phone number is not practical as it must be answered 24/7 by a human being and further, that person will probably be asked for medical advice. Using an address gets the information in writing to the company without having to deal with treatments, etc. The preferred location for this address is in the **Drug Facts** box under Other information. Exact wording is provided. This does not replace the address of your company which is required by FPLA which is outside of the Drug Facts box

This service is available only with a written agreement. This is done as your labels with this address will remain in commerce for as long as 5 years and Report Reaction's requirements remain in effect whenever they are contacted.

For more information, go to [www.reportreaction.com](http://www.reportreaction.com) and fill out the form. This can be faxed to 1-609-799-5271 for a prompt quotation.