From:	Thomas, Terrolyn
To:	"Kristine Riley"
Cc:	Barash, Faith; Lee, Mark H (FDA)
Subject:	Information Request: Pharmacovigilance Plan
Date:	Thursday, July 07, 2011 3:50:19 PM

Hi Kristine:

Please provide a Pharmacovigilance Plan.

For most products, routine pharmacovigilance (i.e., compliance with applicable postmarket reporting requirements under FDA regulations) is sufficient for post-marketing risk assessment. As outlined in Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (http://fda.gov/CDER/guidance/63590CC.htm), FDA believes pharmacovigilance plans may be appropriate when: 1) Serious safety risks have been identified pre- or post-approval, or 2) at risk populations have not been adequately studied. The pharmacovigilance plan is developed by a product's sponsor and is specifically focused on detecting new safety risks and/or evaluating already identified safety risks.

Thanks,
Terrolyn
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