FDA-Industry PDUFA V Reauthorization Meeting
REMS-Sentinel Sub-Group
February 10, 2011, 9:30am - 10:30am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 2388

Purpose

This meeting was the fifth meeting of a negotiation Sub-Group focused on the PDUFA V proposals for Sentinel and for standardizing and integrating REMS into the healthcare system. This meeting focused only on REMS.

Participants

FDA		Industry	
Debbie Henderson	CDER	Jeff Francer	PhRMA
Jane Axelrad	CDER	Florence Houn	Celgene
Claudia Karwoski	CDER	Paul Eisenberg	Amgen
Jayne Ware	CDER	Andrew Emmett	BIO

Measure the Effectiveness of REMS and Standardize and Better Integrate REMS into the Healthcare System

FDA and Industry discussed recent revisions to the REMS proposal. There was a general discussion about the proposal, covering the following topics:

- Whether the proposed commitments would be helpful in addressing some of the overall challenges of the REMS program;
- Challenges in timeliness of managing changes to REMS in both the pre-market and post-market phases; and
- Understanding better how this proposal ties into other proposals being negotiated by the Premarket Sub-Group.

Industry indicated support for the proposal as written given that it provides a framework for addressing key issues. The Sub-Group agreed that the proposal was ready to be presented to the Steering Group as drafted.

There were no substantive proposals, significant controversies, or differences of opinion discussed at this meeting.