FDA-Industry PDUFA V Reauthorization Meeting
March 25, 2011, 2:00pm – 4:30pm
FDA White Oak Campus, Silver Spring, MD
Building 31, Room 2442

Purpose

To review the draft PDUFA V commitment letter and draft proposed statutory changes to reflect additional financial agreements, and associated language to provide justifications for the proposed statutory changes

Participants

FDA		Industry	
Wade Ackerman	CDER	Paul Eisenberg	Amgen
Patrick Frey	CDER	Andrew Emmett	BIO
Debbie Henderson	CDER	Jeffrey Francer	PhRMA
John Jenkins	CDER	Sascha Haverfield	PhRMA
Chris Joneckis	CBER	Kay Holcombe	Genzyme
Brian Kehoe	OL	Paul Huckle	GSK
Donal Parks	CDER	Rob Kowalski	Novartis
Jayne Ware	CDER	Hilary Malone	Pfizer
Bob Yetter	CBER	Sara Radcliffe	BIO
		Jay Siegel	Johnson & Johnson
		Mark Taisey	Eisai
		Helen Thackray	GlycoMimetics
		David Wheadon	PhRMA

FDA and Industry continued discussion of additional edits to the draft PDUFA V commitment letter, the proposed statutory changes, and the justifications for the proposed statutory changes.

In the enhanced review program proposal for NME NDAs and original BLAs, FDA previously agreed to follow existing guidance related to the issuance of discipline review (DR) letters, noting that it would be FDA's goal to complete DR letters in advance of the planned late-cycle meeting. Industry proposed to revise this language to commit FDA to completing all primary and secondary discipline reviews in advance of the late-cycle meeting and providing all DR letters to the sponsor within 8-12 days prior to the late-cycle meeting. FDA stated that these additional commitments were not part of the agreement reached in the Premarket Sub-Group, and that FDA could not agree to a new interim review commitment that all DR letters would be completed by a specified time. Industry stated that companies were seeking assurance that FDA would identify major application issues before the late-cycle meeting to enable a substantive discussion of the issues. FDA reiterated that the agency's clear intent is to conduct a substantive discussion of the sponsor's application at the late-cycle meeting. FDA proposed a revision to state that, in cases where a DR letter is not issued in advance of the late-cycle meeting, the deficiencies identified by that discipline will be communicated in the brief memorandum that is part of the briefing package for the late-cycle meeting. Industry accepted this revision.

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