

Figure 1: Subpart H Analysis Keyed to Factors in FDA's Draft Guidance on Expedited Programs
 By Frank Sasnowski and Alexander Varoud to FDA, August 26, 2013

Drug	Part 1: Regulatory Factors Weighing into FDA Determination (Section VII.C.1) ¹					Part 2: Understanding of the Disease Process (Section VII.C.1.a) ¹	Part 3: Understanding of the Relationship between the Drug's Effect on Surrogate and the Disease (Section VII.C.1.b) ¹	Part 4: Strength of Clinical Evidence (Section VII.C.1) ¹		Total
	Statutory Factors		External expertise (0-1)	Surrogate Endpoint (0-4)	Clinical Benefit (0-3)					
	Severity (0-2)	Rarity (0-2)								
1. Sirturo	2	2	2	1	2	2	3	-1	13	
2. Fenpropion	2	2	2	1	3	2	4	0	16	
3. Maltena	2	2	1	1	1	3	4	1	15	
4. Promacta	2	2	2	0	2	1	4	1	14	
5. Espado	2	2	2	3	3	2	2	0	14	
6. Levatolol	2	2	1	1	3	2	4	1	16	
7. Tyabril	2	2	2	0	2	3	4	1	16	
8. Luventis	2	2	2	1	1	2	2	2	14	
9. Falsarizyme	2	2	2	1	3	1	4	0	15	
10. Remodulin	2	2	2	1	3	1	3	1	15	
11. Cipro	2	2	2	2	3	2	4	1	17	
12. Celebrex	2	2	2	1	3	3	4	0	17	
13. Synercid	2	1	2	1	3	2	2	0	13	
14. Remicade	2	2	2	1	1	1	3	0	12	
15. Priftin	2	2	2	1	2	2	2	0	13	
16. Sulfamylon	2	2	2	1	3	2	1	0	13	
17. Proloamline	1	2	2	0	3	2	3	0	13	
18. Bilein	2	1	2	1	2	1	2	1	12	
19. Betaseron	2	2	2	1	2	2	4	2	17	
	Range for Part 1: 4 to 7 (out of 7)					Range for Part 2: 1 to 3 (out of 3)	Range for Part 3: 1 to 3 (out of 3)	Range for Part 4: 1 to 5 (out of 7)		

Statistics	Score
Average Score	14.5
Min	12
Max	17
Median	14
SD	1.7

¹These citations are to the FDA Draft Guidance
²Parts 2, 3, and 4 are also from FDC Act Sec. 506, as amended by FDASIA Sec. 801, specifically, FDASIA uses the following terms for each of these parts:
 - Part 2 relates to "pathophysiological" evidence
 - Part 3 relates to "epidemiological, ... pharmacological, or other evidence ..."
 - Part 4 relates to "therapeutic" evidence