Figure 1: Subpart H Analysis Keyed to Factors in FDA's Draft Guidance on Expedited Programs

By Frank Sasinowski and Alexander Varond to FDA, August 26, 2013

Drug	Part 1: Regulatory Factors Weighing Into FDA Determination (Section VII.C.1)[1]				Part 2:[2] Understanding of the Disease Process (Section VII.C.1.a)[1]	Part 3:[2] Understanding of the Relationship between the Drug's Effect on Surrogate and the Disease (Section VII.C.1.b)[1]	Part 4:[2] Strength of Clinical Evidence (Section VII.C.1)[1]		Total
	Statutory Factors			External expertise (0-1)	Understanding of the Disease (0-3)	Epidemiological, Pharmacologic, and "Other Evidence" on the Surrogate or Disease (0-3)	Surrogate Endpoint (0-4)	Clinical Benefit (0-3)	
	Severity (0-2)	Rarity (0-2)	Unmet Need (0-2)						
1. Sirturo	2	2	2	1	2	2	3	-1	13
2. Ferriprox	2	2	2	1	3	2	4	0	16
3. Makena	2	2	1	1	1	3	4	1	15
4. Promacta	2	2	2	0	2	1	4	1	14
5. Exjade	2	2	2	1	3	2	2	0	14
6. Levaquin	2	2	1	1	3	2	4	1	16
7. Tysabri	2	2	2	0	2	3	4	1	16
8. Luveris	2	2	2	1	1	2	2	2	14
9. Fabrazyme	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	1	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. ProAmatine	1	2	2	0	3	2	3	0	13
18. Biaxin	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)		

[1] These citations are to the FDA Draft Guidance

[2] Parts 2, 3, and 4 are also from FDC Act Sec. 506, as amended by FDASIA Sec. 901, specifically, FDASIA uses the following terms for each of these parts:
- Part 2 relates to "pathophysiological" evidence
- Part 3 relates to "epidemiological, . . . pharmacologic, or other evidence . . ."
- Part 4 relates to "therapeutic" evidence

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