Specialty Pharmacy Solutions - **Client Alert** - 10/24/2016

2016 FDA Approvals Lag 2015 Pace ©

One of the reasons that Amazon.com does so well is the plethora of new products that it offers. Customers want every new gadget (*otherwise known as "I gotta have that!*).
The same applies to specialty pharmacy…. new products have been a huge factor in the YOY growth in the industry. And the gatekeeper for all those new wonder drugs (*spell that r e v e n u e g e n e r a t o r s*) is the FDA.

2015 was a banner year for specialty pharmacy new drug approvals (*not to mention a boat load of new indications for previously approved meds*).
2016 arrived with high anticipation of another record breaking year…… *well hold yer horses*. So far 2016 is way off the pace. Eleven of only 18 drugs approved through last week are specialty pharmacy therapies -- *curiously, the FDA missed listing Inflectra, the biosimilar copy of Remicade approved on 10/18*. So, with only another 10 weeks to go in this year, the FDA is going to have to put pedal to the metal to catch up to last year's record.

It is a bit hard to understand. It's not for a long line of therapies waiting for review and approval…… the pipeline is full.
And, given all the public pressure to expedite new drug approvals it would seem that the FDA would be cranking out approvals almost daily. Not so. It is even more confusing considering that Exondys 51 for Duchenne Muscular Dystrophy met <u>huge</u> resistance within the FDA…. yet did get approval last month.

The list below details the 2016 approvals.
Add in <u>approvals of **biologics** and you find that there have only been 4 approved this year</u> and only two fall under specialty pharmacy, Kovaltry and Idelvion – both for hemophilia (*Factor VIII and factor IX respectively*).

As Alice would have said…."Curiouser and curiouser".

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Certain drugs are classified as new molecular entities ("NMEs") for purposes of FDA review. Many of these products contain active moieties that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product; these products frequently provide important new therapies for patients. Some drugs are characterized as NMEs for administrative purposes, but nonetheless contain active moieties that are closely related to active moieties in products that have previously been approved by FDA.
For example, CDER classifies biological products submitted in an application under section 351(a) of the Public Health Service Act as NMEs for purposes of FDA review, regardless of whether the Agency previously has approved a related active moiety in a different product. FDA's classification of a drug as an "NME" for review purposes is distinct from FDA's determination of whether a drug product is a "new chemical entity" or "NCE" within the meaning of the Federal Food, Drug, and Cosmetic Act.

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date

18.	Lartruvo	olaratumab	10/19/2016	To treat adults with certain types of soft tissue sarcoma Press Release
17.	Exondys 51	eteplirsen	9/19/2016	To treat patients with Duchenne muscular dystrophy Press Release Drug Trials Snapshot
16.	Adlyxin	lixisenatide	7/27/2016	To improve glycemic control (blood sugar levels) Press Release
15.	Xiidra	lifitegrast ophthalmic solution	7/11/2016	To treat the signs and symptoms of dry eye disease Press Release
14.	Epclusa	sofosbuvir and velpatasvir	6/28/2016	To treat all six major forms of hepatitis C virus Press Release Drug Trials Snapshot
13.	NETSPOT	gallium Ga 68 dotatate	6/1/2016	A diagnostic imaging agent to detect rare neuroendocrine tumors Press Release Drug Trials Snapshot
12.	Axumin	fluciclovine F 18	5/27/2016	A new diagnostic imaging agent to detect recurrent prostate cancer Press release Drug Trials Snapshot
11.	Ocaliva	obeticholic acid	5/27/2016	To treat rare, chronic liver disease Press release Drug Trials Snapshot

10.	Zinbryta	daclizumab	5/27/2016	To treat multiple sclerosis Press Release Drug Trials Snapshot
9.	Tecentriq	atezolizumab	5/18/2016	To treat urothelial carcinoma, the most common type of bladder cancer Press Release Drug Trial Snapshot
8.	Nuplazid	pimavanserin	4/29/2016	To treat hallucinations and delusions associated with psychosis experienced by some people with Parkinson's disease Press Release Drug Trial Snapshot
7.	Venclexta	venetoclax	4/11/2016	For chronic lymphocytic leukemia in patients with a specific chromosomal abnormality Press Release Drug Trials Snapshot
6.	Defitelio	defibrotide sodium	3/30/3016	To treat adults and children who develop hepatic veno-occlusive disease with additional kidney or lung abnormalities after they receive a stem cell transplant from blood or bone marrow called hematopoietic stem cell transplantation Press Release Drug Trials Snapshot
5.	Cinqair	reslizumab	3/23/2016	To treat severe asthma Press Release Drug Trials Snapshot
4.	Taltz	ixekizumab	3/22/2016	To treat adults with moderate-to-severe plaque psoriasis.

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3.	Anthim	obiltoxaximab	3/18/2016	To treat inhalational anthrax in combination with appropriate antibacterial drugs. Press Release Drug Trials Snapshot
2.	Briviact	brivaracetam	2/18/2016	To treat partial onset seizures in patients age 16 years and older with epilepsy. Press Release Drug Trials Snapshot
1.	Zepatier	elbasvir and grazoprevir	1/28/2016	To treat patients with chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adult patients. Press Release Drug Trials Snapshot

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