June Approvals Soar, Receipts Down - A Good Month for OGD

June 2015 saw the largest number of approvals in a single month since the start of GDUFA, at 57 full approvals and 10 tentative approvals, while receipts were a meager 37. This reverses a long trend of receipts outpacing approvals and represents a month where the backlog actually has an absolute decrease of at least 30 applications. Compare this to September 2012, when OGD approved 68 ANDAs (which was the last month that approvals were higher than the June 2015 figure) and issued 11 tentative approvals, but received 159 ANDAs. Good news for the Office of Generic Drugs (OGD) and the Office of Product Quality (OPQ), but is it enough to put a smile on the industry’s face?

With a backlog (including ANDAs currently at FDA awaiting action and those with Complete Response Letters (CRLs) outstanding with industry) totaling about 4000, an absolute decrease of 30 a month will hardly dent this backlog, but it is clearly a move in the right direction.

If the approval numbers continue to climb and receipts stay low, that will bode well for the “backlog” ANDAs (those submitted prior to October 1, 2012) and those in cohort years 1 and 2, as resources will become available and OGD should better be equipped to meets its GDUFA goals for cohort year 3 ANDAs, thus, spending more review time on the older ANDAs.

However, trying to get a handle on current amendment receipts is difficult at best. Looking at the old OGD statistical reports, receipts of amendments were listed at about 170 a month; under the new reporting system that number is somewhere around 400 a month. Whether the discrepancy is due to the old reporting system not capturing all amendments (solicited, unsolicited, and administrative) is unknown. Today, amendments to CRLs, responses to information requests, receipt of solicited and unsolicited amendments, and administrative amendments are all being tracked and counted. Remember, OGD’s hope is to move ANDAs towards approval when possible and not just issue CRLs to meet GDUFA goals to help reduce the number of review cycles, and thus, increase efficiency in the review and approval process.

Supplements represent another large bucket of work for OGD and OPQ. Pre-GDUFA, receipts of supplements historically outpaced supplemental approvals, and thus, the supplemental backlog grew to over 5000. Under the new reporting system, we can see what appears to be a surge in supplemental submissions, but, unfortunately, there are no figures describing numbers of approvals and CRLs for supplements, so it is difficult to understand where OGD is in knocking down that backlog, albeit that OGD has indicated that the supplemental backlog has significantly decreased.

As we hope for the best, let’s give a hand to OGD for their productivity in the last few months and hope the review and approval machine continues to spit out more and more approvals as OGD moves closer to cohort year 4 submissions and more rigorous goal dates. In the meantime, I have a couple of questions for our readers; 1) are you seeing Target Action Dates (TADs) being assigned to older applications as promised by OGD? and 2) are you seeing PAS actions moving faster under the year 3 goals? Please let me hear from you at r.pollock@lachmanconsultants.com