"The Pink Sheet" DAILY

FDA Approves Its First 'Clocked' ANDA

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Executive Summary

Application for an acne medication is first to be approved with a formal review goal under GDUFA, and comes five months early.

FDA approved its first ANDA with a GDUFA review goal date in style – about five months early.

Agency officials confirmed Aug. 19 that the ANDA for Tretinoin Gel filed by **Spear Pharmaceuticals Inc.** was cleared Aug. 13.

The review took slightly longer than 10 months, FDA told "The Pink Sheet" DAILY. It was well ahead of the 15-month goal set for some ANDAs filed in fiscal year 2015.

The generic drug user fee program established ANDA goal dates starting in FY 2015. Sixty percent of ANDAs submitted this fiscal year, which began Oct. 1, 2014, have to be acted upon within 15 months.

The agency said the early approval was a testament to the potential for the new generic drug user fee program and the reward for submitting a quality application.

"This approval can serve as an example of what can be achieved through good communication and integration of effort on an application that is complete and free of issues requiring multiple information requests or complete responses," the agency said in an email.

Tretinoin Gel is a topical treatment for acne vulgaris. Several generic cream and gel formulations already have been approved, including some marketed by Spear.

FDA said the application filing portion of the review took a little more than 30 days, just more than half of the 60-day FDA target.

Agency staff also completed their review of the clinical endpoint bioequivalence study in about eight months.

FDA said that process can take more than 15 months because of the complex statistical analysis required. But the agency said new processes in the Office of Generic Drugs' Office of Bioequivalence Division of Clinical Review, along with help from the Office of Biostatistics, allowed a faster completion.

The agency's Office of Pharmaceutical Quality completed all chemistry, manufacturing and controls reviews, including the facility inspections, in about six months.

"The new and more efficient processes for review that have been put in place during the massive reorganizations of OGD and OPQ are bearing fruit," the agency said.

FDA made a number of changes to meet its GDUFA responsibilities, including hiring more than 1,000 employees and changing communications and other practices ("GDUFA Success Story: FDA Exceeds Hiring Goals, Names OGD Director" — *"The Pink Sheet" DAILY,* Jan. 15, 2015).

Approval Bodes Well For Long-Term Performance

The quick approval suggests good prospects for OGD reviewers to meet their ultimate GDUFA I goal, which is a 10-month review.

In FY 2016, 75% of ANDAs submitted that year have to receive an action within 15 months.

In FY 2017, the final year of GDUFA I, 90% of ANDAs received during the year must be acted upon within 10 months ("GDUFA Performance Goals For Fiscal Years 2013-2017" — *"The Pink Sheet,"* Dec. 12, 2011).

Success is measured by OGD actions, which are an approval or ANDA tentative approval, "complete response" letter or refuse-to-receive action.

OGD wants to focus on approvals, however ("FDA Generics Office Sets Aspirational Goal To Clear Unmeasured ANDAs" — *"The Pink Sheet" DAILY,* Dec. 12, 2014).

Approval Comes With Communications Changes

The clocked review substantially differs from the experiences described by many sponsors following GDUFA's launch.

During the first two years of GDUFA, before applications received formal review goals, sponsors complained that average review times continued to increase and information about an ANDA review status was difficult to obtain ("ANDA Reviews: First-Cycle Desired, But Two-Cycles OK?" — *"The Pink Sheet,"* Jul. 27, 2015).

News of the approval came on the heels of FDA's release of a new communications policy for the ANDA reviews.

The new Manual of Policies and Procedures document is intended to increase information flow and transparency, especially for sponsors whose applications do not have formal review goals.

[*Editor's Note: Look for more coverage of the new ANDA communications MaPP in the next edition of "The Pink Sheet."*]

FDA's ANDA review success also should help with GDUFA reauthorization negotiations, which are expected to begin this fall ("GPhA Warns FDA On ANDA Review Transparency" — *"The Pink Sheet" DAILY,* Aug. 13, 2015).

Overall, OGD has seen an increase in its approval output during the last few months, including the largest total for a single month since GDUFA launched ("ANDA Approvals Continue To Accelerate As FDA Breaks Monthly Record" — *"The Pink Sheet" DAILY,* Aug. 7, 2015).