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CPhI expert calls for ANDA approvals to be reduced by two-thirds in order to lower drug costs

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FDA or US legislature has to intervene and assure that necessary samples are available to potential generic companies to complete necessary studies for approval



Girish Malhotra, President of EPCOT International, and CPhI Worldwide Annual Industry Report member, discusses the necessity of time reduction for ANDA approvals, arguing that if the current approval time can be reduced from ten months to three months, drug costs will decrease.

He said, “In order to decrease the time for ANDA approvals, there are three main challenges to overcome. Currently, it takes up to four review cycles to approve an ANDA, and the first and foremost challenge is with submission completeness.”

“On average, it takes the FDA reviewing team 45 days to determine application completeness. This time can potentially be reduced to 15 days if the FDA modifies their review process. Last month the Pre-ANDA program was proposed, a first-step Quality by Analysis (QbA) implementation in the application filing process. Although applications for every product are different in content, the information filing requirements are essentially the same. Workshops that train the FDA industry staff to become familiarized with the application requirements would allow the Pre-ANDA program to be implemented efficiently”, Malhotra explained.

“If the approval process were lowered to three months, the need for priority review would likely disappear entirely”, he added

Lastly, the 90-day frame can be further broken down into three segments. The FDA will complete the initial review within 15 days and companies would then have 30 days to respond to FDA’s requirements. Following this, the FDA will then have 45 days to review the application and return to the company with a final proposal. Companies that cannot fulfill obligations after the 15-day FDA review combined with the 30-day deficiency completion will be required to start the process over. This will encourage companies to ensure that they provide the best application possible.