

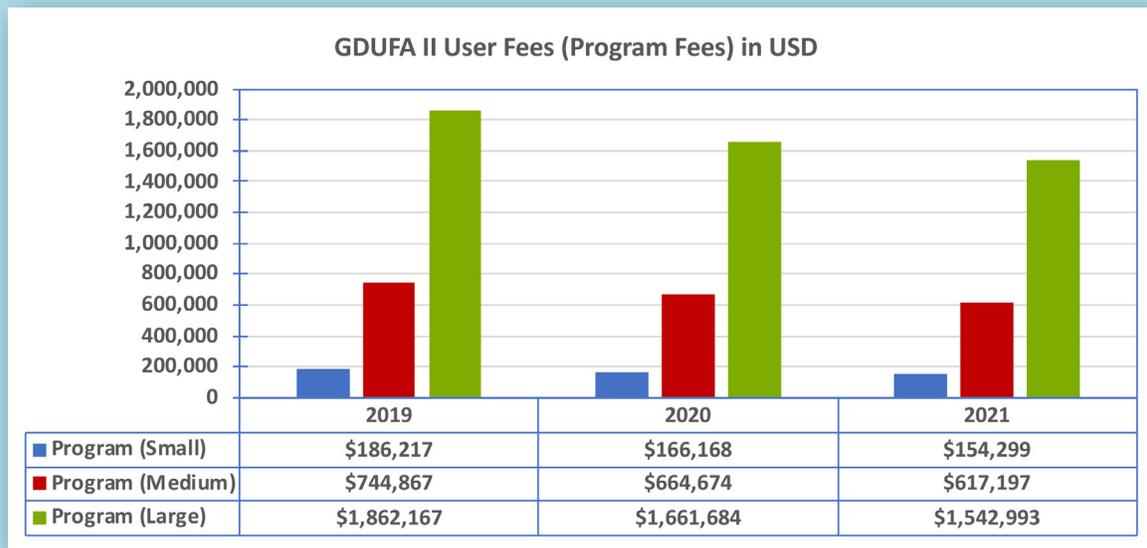
Park Unused ANDAs Here

For GDUFA II Program Fee Relief



GDUFA II User Fees: They Saved Paradise and Put Up a Parking Lot

The Generic Drug User Fee Amendments (“GDUFA”) payment due date IS FAST APPROACHING — Thursday, October 1, 2020 — and companies are trying to plan ahead now to see if there's a way to reduce costs and save money for FY 2021. Fees can be dramatic and impactful just to keep the assets you own already and worked so hard to develop or acquire.



This is true especially for a company in the small and medium size operation tiers—and perhaps one or two in the large size operation tier — seeking a way to potentially save significant program fees. A few years ago, a system dubbed “ANDA Arbitrage” was introduced by a company called **ANDA Repository, LLC** in an effort to help companies potentially decrease annual user fee liability under GDUFA II.

Imagine a parking lot. The owner of a car that is not being used on a daily basis needs a parking space for that car. In exchange for that parking space (and an annual fee) the car's owner transfers title of the automobile to the parking lot owner. The former owner of the car can, with appropriate notice, take back ownership when he decides he wants to use the automobile again. Provided the parking lot owner has enough cars in the lot, this can be a beneficial venture for all of the parties involved.

In the imagery above, the automobile owner is an ANDA sponsor (typically with a discontinued, but not withdrawn approval, ANDA), and the parking lot owner and attendant is **ANDA Repository, LLC**. As a “large size” operation, ANDA Repository, LLC pays a flat GDUFA II ANDA Holder Program Fee regardless of how many ANDAs are owned. In exchange for its services, ANDA Repository, LLC charges an ANDA sponsor an annual fee, which is significantly less than the ANDA Holder Program Fee the ANDA sponsor would otherwise pay as a small or medium size operation.

If you're interested in the program, please reach out to ANDA Repository, LLC soon. The mechanism to communicate to the FDA a transfer in ANDA ownership well prior to October 2020 is relatively painless. Also please check with us before WITHDRAWING your ANDAs. There were 388 ANDA Withdrawals last fiscal year, which is like burning your own assets. Unless mandated to do so, **ANDA Repository** is a far better option, and we may be interested in purchasing them from you outright. Contact us NOW!!!

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