

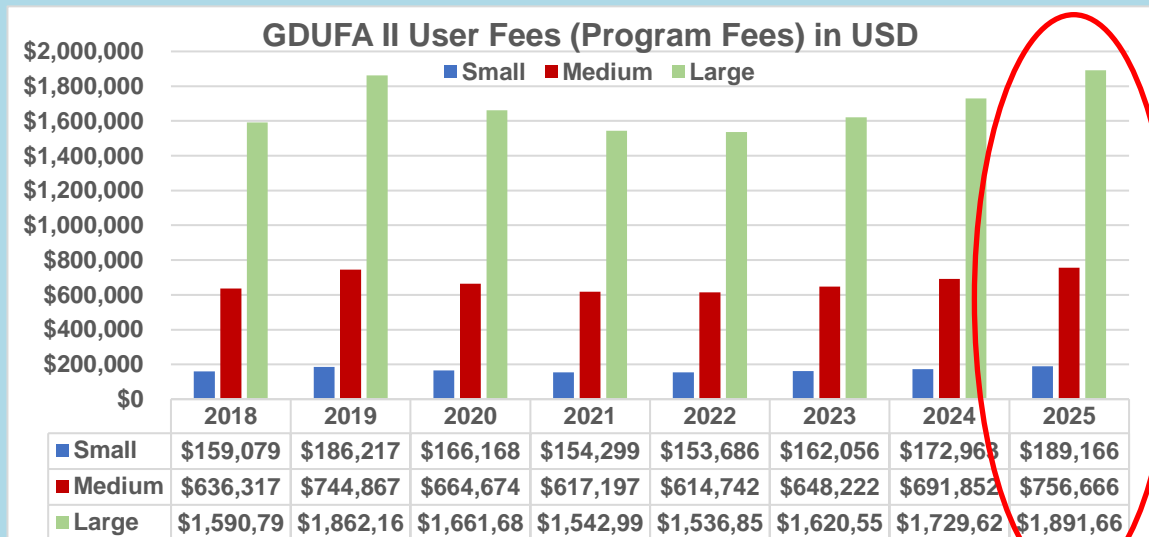
# Park Unused ANDAs Here

## For GDUFA III Program Fee Relief



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

The Generic Drug User Fee Amendments (“GDUFA III”) payment due date is fast approaching on October 1, 2024 and companies are planning ahead now to reduce costs for FY 2025. Fees can be substantial 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 III.

Imagine a parking lot. The owner of a car that is not being used on a daily basis needs a 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 car 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In the imagery above, the automobile owner is an ANDA sponsor (typically with a discontinued, but not withdrawn approval, ANDA), and the parking lot owner and attendant is **ANDA Repository, LLC**.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 III 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 2024 is relatively painless. Also please check with us before withdrawing your ANDAs. There were 172 ANDA Withdrawals in fiscal year 2023, 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!