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FDA User Fee Checklist: FY 2022 Edition

- Have you identified the appropriate regulatory submission pathway for your device (e.g, 510(k), PMA, De Novo)?
- Have you verified the FY 2022 user fee applicable to your submission type?
- Have you checked your eligibility for small business certification?
- Have you submitted Form FDA 3602 (U.S.-based firms) or Form FDA 3602A (non-U.S. firms) for small business status, if applicable?
- Have you determined whether your submission qualifies for any fee exemptions or reductions (e.g., HDE, Third-Party 510(k))?
- Have you prepared the budget for the annual establishment registration fee (FY 2022: $5,672), if applicable??
- Have you generated the User Fee Cover Sheet (Form FDA 3601) and arranged payment before submission?
- Have you planned your submission timing to align with the fiscal and budgeting strategy?
- Are all internal stakeholders informed of U.S. Food and Drug Administration user fee requirements under MDUFA?