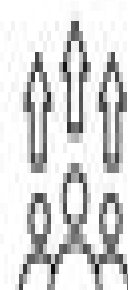
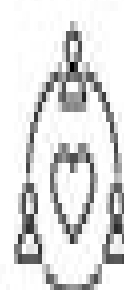
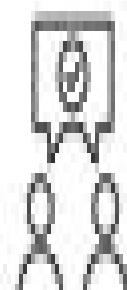
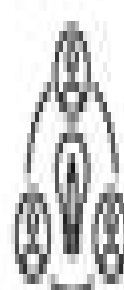
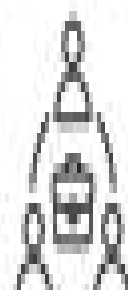
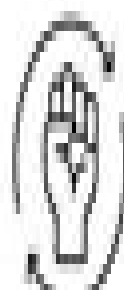
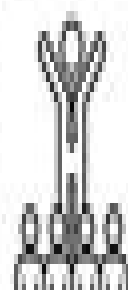
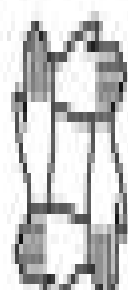
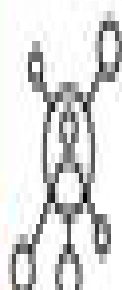
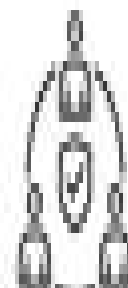
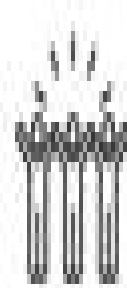
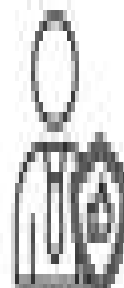
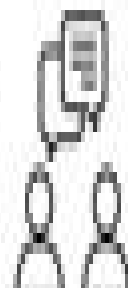
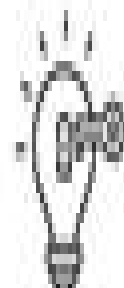
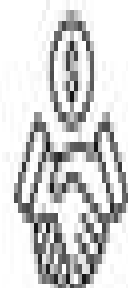
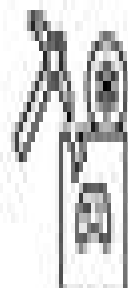
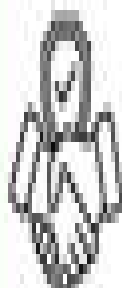
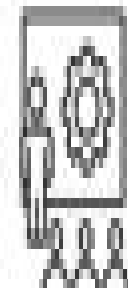
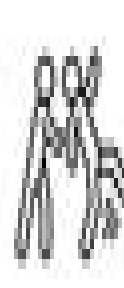
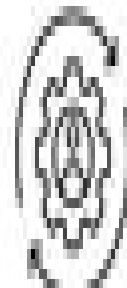
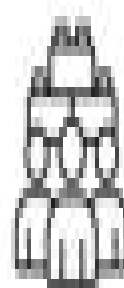
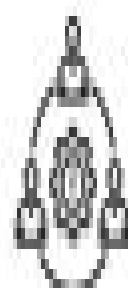
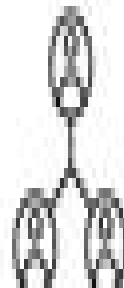
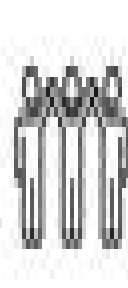
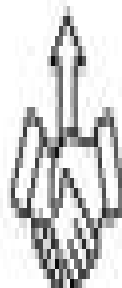
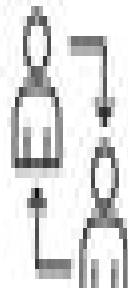




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web nov 25 2019 an abbreviated new drug application anda contains data which is submitted to fda for the review and potential approval of a generic drug product once approved an applicant may manufacture and market the generic drug product to provide a safe effective lower cost alternative to the brand name drug it references

**guidance for industry u s food and drug administration** - Mar 08 2023

web the nda anda aada holder should follow the procedure outlined in form fda 2252 when filing an annual report annual reports should be filed for all approved nda s inserts and examples of the

**cfr code of federal regulations title 21 food and drug administration** - Jul 12 2023

web jun 7 2023 sec 314 81 other postmarketing reports a applicability each applicant shall make the reports for each of its

approved applications and abbreviated applications required under this section and section 505 k of the act b reporting requirements the applicant shall submit to the food and drug administration at the specified times two

**regulatory resources duke university school of medicine 26 nda** - Sep 02 2022

web template documents these template documents are intended to teach as a steer for preparation of regulatory offers to the fda additional regulated tools and educational resources for academic researchers live accessible on aforementioned regardd website

**postmarketing requirements and commitments frequently** - Aug 13 2023

web are nda and anda applicants required to submit an annual report are bla applicants required to submit an annual report when and how often must an applicant submit an annual

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web cbe 0 or annual report for notifying the agency of the changes 7 under 21 cfr 314 70 a 3 an applicant is required to make a change in accordance with a regulation or