**Drug Review Template**

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| **Drug Name** |  |
| NDA # (Sponsor) |  |
| Indication:  Mechanism of Action: |  |
| Dosage form |  |
| Classification (505b1, 505 b2, 505J) |  |
| Number of Clinical Studies Needed for Approval |  |
| Phase 1 |  |
| Phase 2 |  |
| Phase 3 |  |
| Final Safety Database |  |
| Where pediatric studies done or a waiver asked for? |  |
| Nonclinical studies |  |
| Any CMC issues |  |
| How many time was the NDA submitted before the drug/biologic got approval |  |
| If rejected after the first submission, what were the reasons for the non-approval? |  |
| How long was it between the 1st NDA submission & the final approval of the drug? |  |
| What was the tone of the communication with FDA? |  |
| What were the proposed and final tradenames? |  |