ABBREVIATED NEW DRUG APPLICATION FILING

(ANDA) Introduction

- An Abbreviated New Drug Application (ANDA) contains data submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, for review and ultimate approval of a generic drug product.
- Once ANDA is approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the public.
- A generic drug product is the one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

- Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).

- Use of bioequivalence as the base for approving generic drug products was established by the "Drug Price Competition and Patent Term Restoration Act of 1984," also known as the WAXMAN-HATCH ACT.

Guidance Documents for ANDAs

Guidance documents to help prepare ANDAs are listed together in the following categories:

1. Generics :

- Generics (Draft - Distributed for comment purposes only).
- Procedural Draft: Applications Covered by Section 505(b)(2). This provision permits FDA to rely, for approval of an NDA, on data not developed by the applicant.

2. Biopharmaceutics:

- Bioavailability and Bioequivalence Studies for Orally Administered Drug Products -

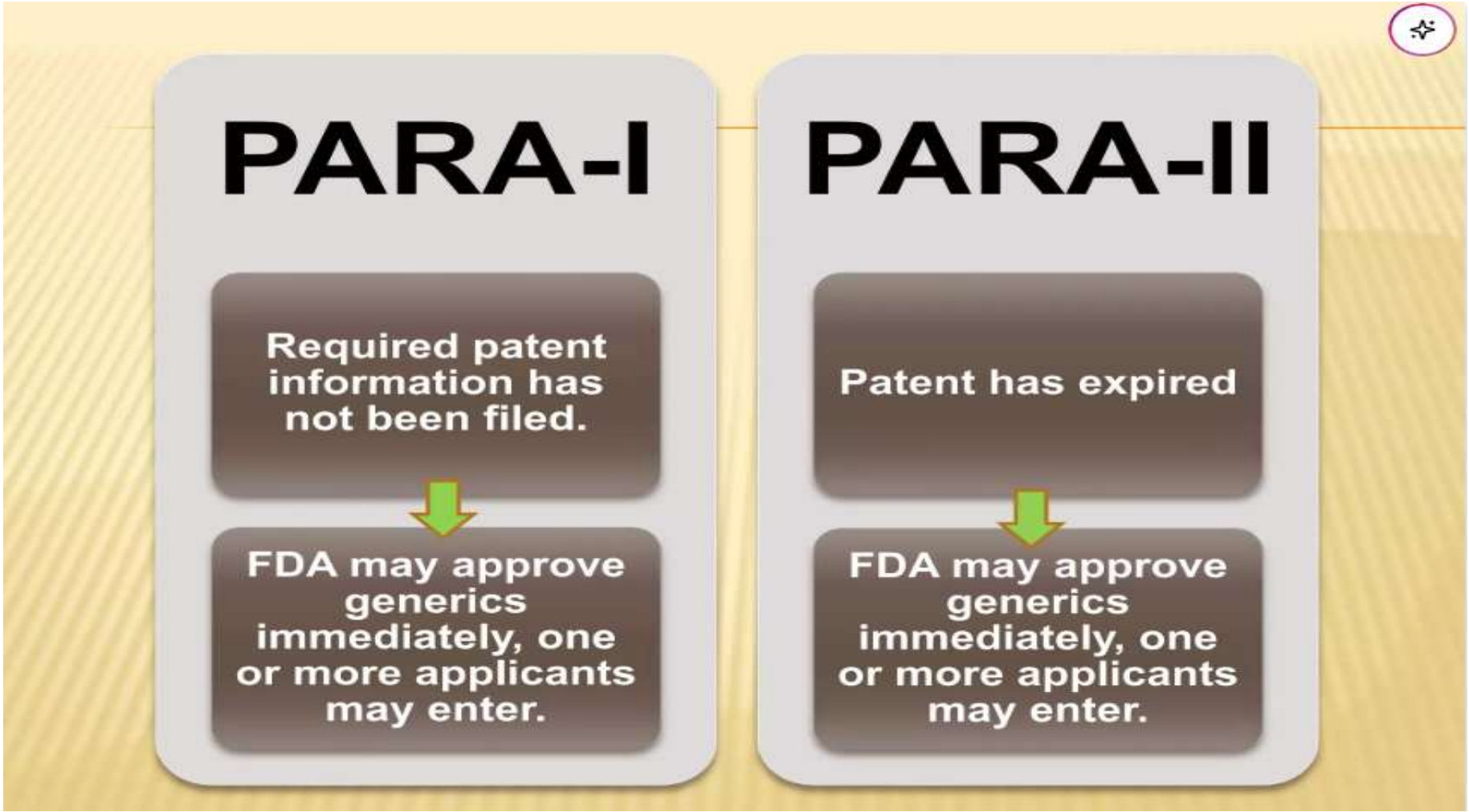
3. Drug Master Files.

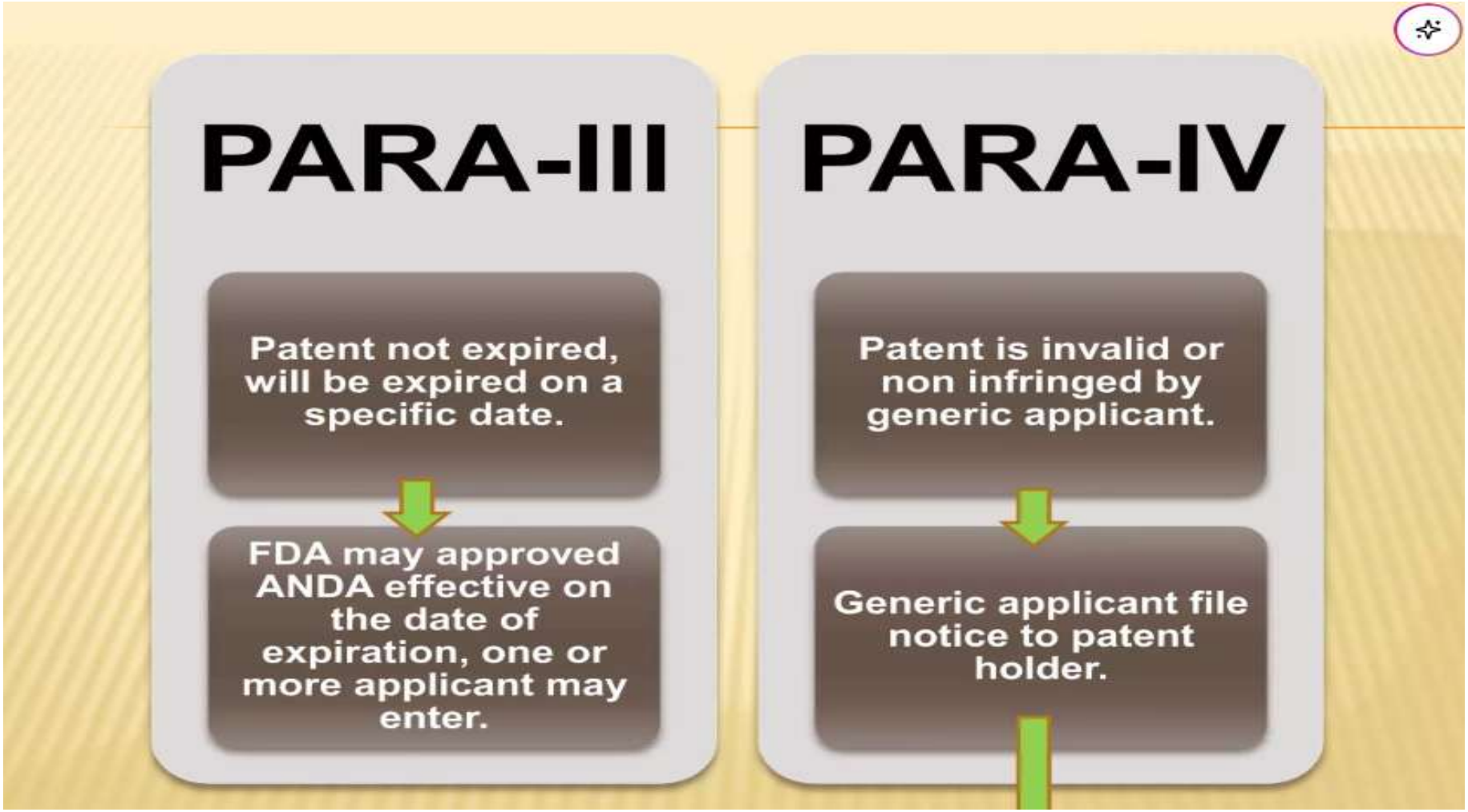
4.Guidance for Industry: Changes to an Approved NDA or ANDA

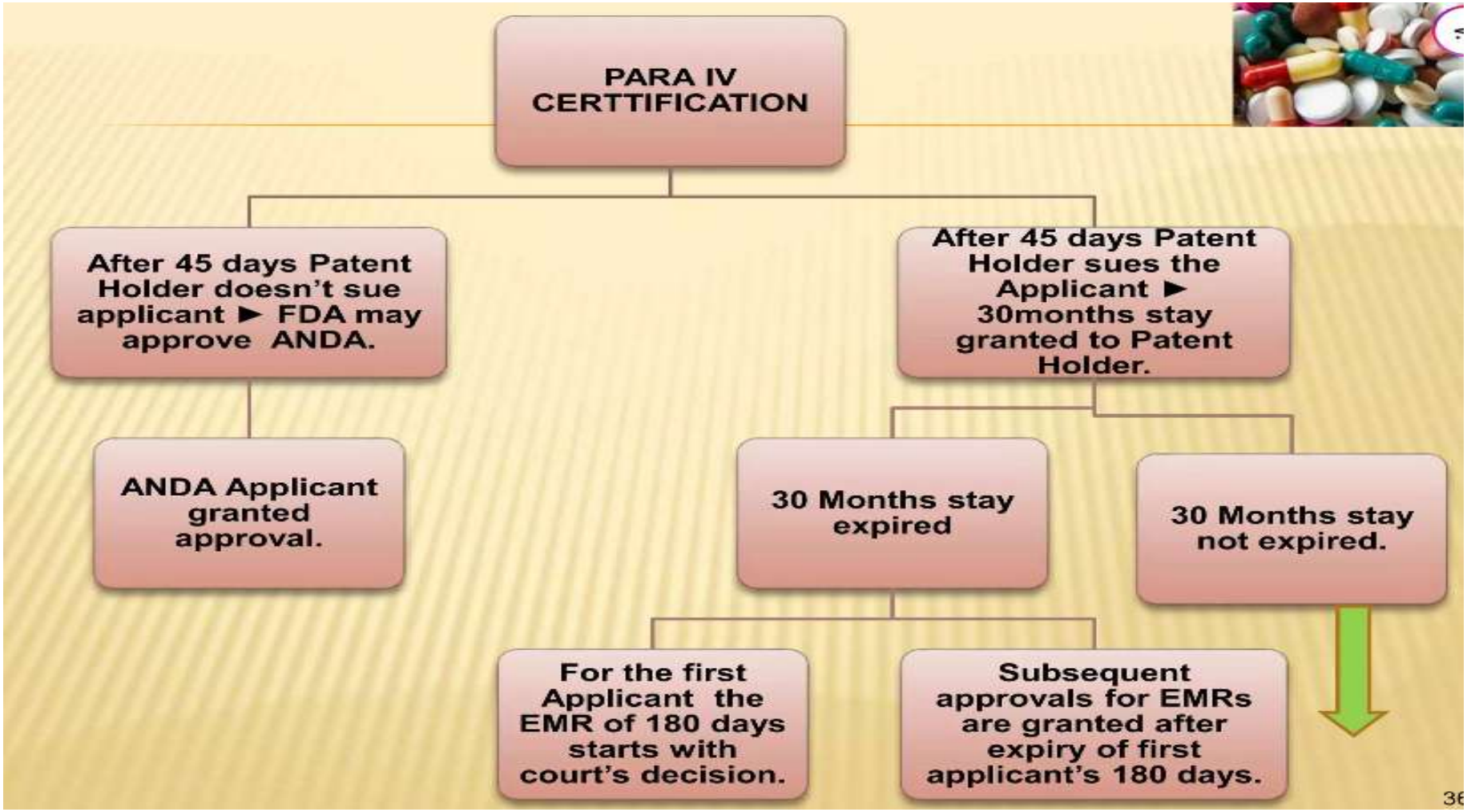
5.Refusal to Receive: Clarifies CDER's decisions to refuse to receive an incomplete application.

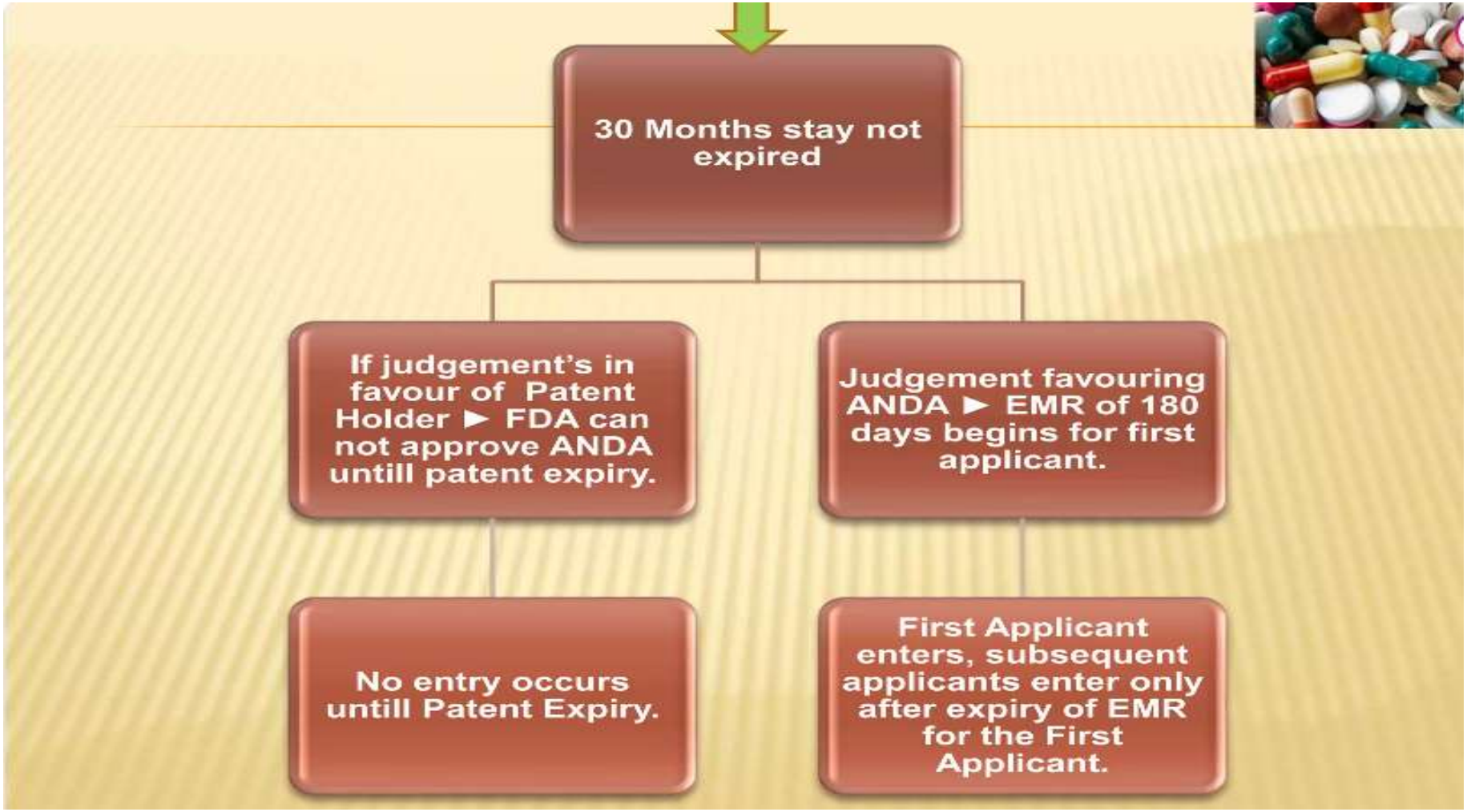
6.Inactive Ingredient Database: This database contains all inactive ingredients present in approved drug products or conditionally approved drug products currently marketed for human use.

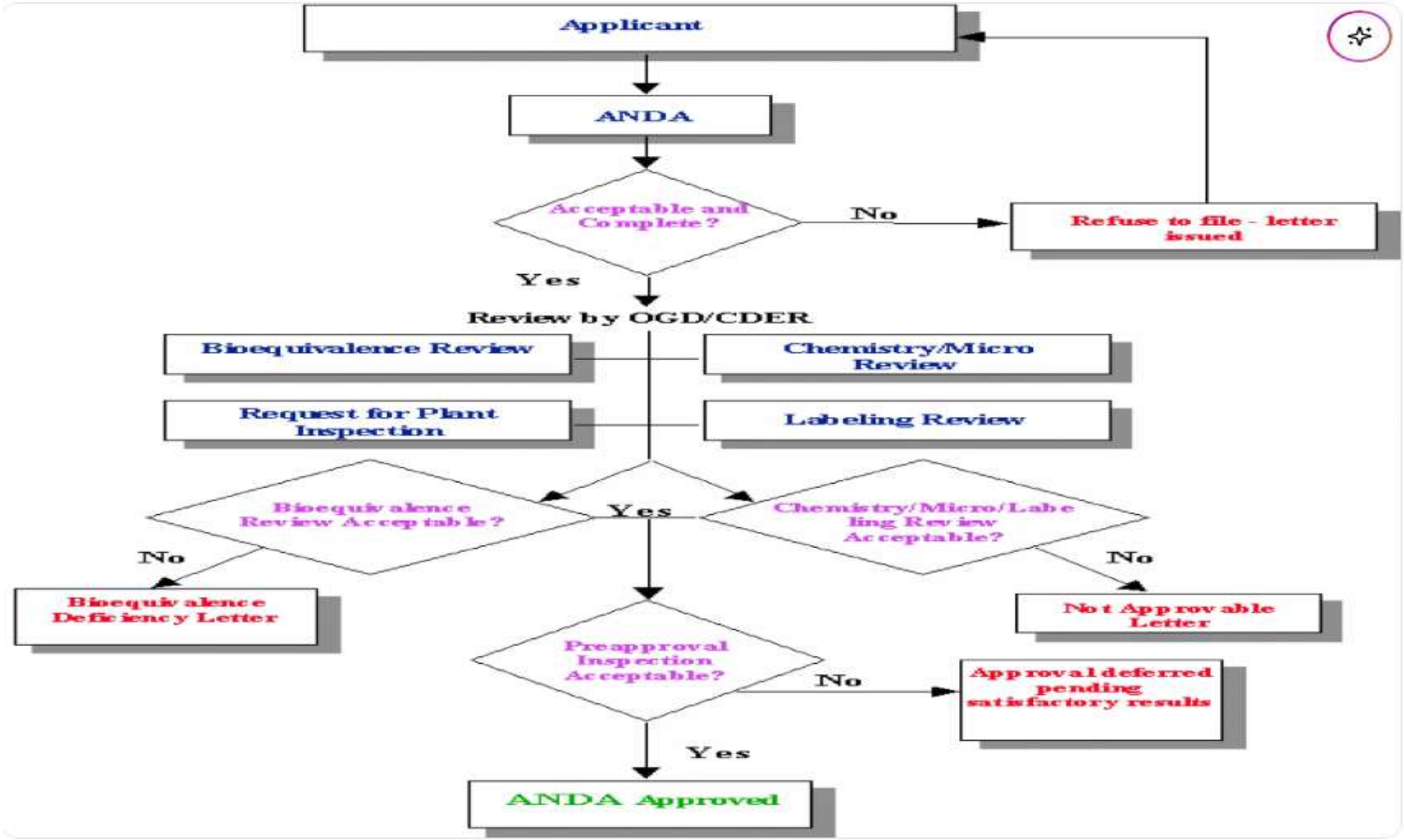

ANDA CERTIFICATION CLAUSES
PARAGR APH I
PARAGR APH II
PARAGR APH III
PARAGR APH IV


PARA-I
Required patent information has not been filed.
FDA may approve generics immediately, one or more applicants may enter.
PARA-II
Patent has expired
FDA may approve generics immediately, one or more applicants may enter.


PARA-III
Patent not expired, will be expired on a specific date.
FDA may approved ANDA effective on the date of expiration, one or more applicant may enter.
PARA-IV
Patent is invalid or non infringed by generic applicant.
Generic applicant file notice to patent holder.


PARA IV CERTTIFICATION
After 45 days Patent Holder doesn't sue applicant ► FDA may approve ANDA.
ANDA Applicant granted approval.
After 45 days Patent Holder sues the Applicant ► 30months stay granted to Patent Holder.
30 Months stay expired
30 Months stay not expired.
For the first Applicant the EMR of 180 days starts with court's decision.
Subsequent approvals for EMRs are granted after expiry of first applicant's 180 days.


30 Months stay not expired
If judgement's in favour of Patent Holder ► FDA can not approve ANDA untill patent expiry.
Judgement favouring ANDA ► EMR of 180 days begins for first applicant.
No entry occurs untill Patent Expiry.
First Applicant enters, subsequent applicants enter only after expiry of EMR for the First Applicant.


Applicant
ANDA
Acceptable and Complete?
No
Refuse to file - letter issued
Yes
Review by OGD/CDER
Bioequivalence Review
Chemistry/Micro Review
Request for Plant Inspection
Labeling Review
Bioequivalence Review Acceptable?
Yes
Chemistry/Micro/Labeling Review Acceptable?
No
No
Bioequivalence Deficiency Letter
Not Approvable Letter
Preapproval Inspection Acceptable?
No
Approval deferred pending satisfactory results
Yes
ANDA Approved