Suitability Petitions Enable Generics

9/21/2022

Robert Lionberger

Director, Office of Research and Standards

Advancing Generic Drug Development: Translating Science to Approval

Maximize J

- For public health, to increase access to medications and for the efficiency of the drug development system as a whole, we should **Maximize J**
- Use the 505(j) application process whenever it can be used
  - No unnecessary human studies
  - The most efficient FDA review process
  - Focus new drug development on new therapeutics and not regulatory games

Allowed Suitability Petitions

- A different active ingredient in a combination product in which the other active ingredients match those of the reference listed drug (RLD)
- A different route of administration
- A different dosage form
- A different strength

Reasons to Deny Petitions

- API Changes
  - Changes to an API in a single ingredient product
  - The petition does not contain information to show that the different active ingredient of the drug product is of the same pharmacological or therapeutic class as the ingredient of the RLD
  - The different active ingredient is not an active ingredient in a listed drug
  - The remaining active ingredients are not identical to those of the listed combination drug
- Any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem
- FDA has determined that the RLD has been withdrawn from sale for safety or effectiveness reasons
- FDA will not approve when an NDA has been approved for the same change
- Summary: FDA will not approve suitability petitions that need new clinical data

Value of Suitability Petitions

- Allow the generic industry to fill market needs or opportunities without new clinical data
  - Convenience of dosing for patients (no tablet splitting, ease of swallowing)
  - Efficiency of dosing for health care providers (no waste because containers are right sized for current use)
- New strengths or presentations that respond to new ways of using established drugs
  - **A characteristic of a flexible and adaptable drug development system**

Limitations

- FDA takes too long to evaluate/approve suitability petitions
- FDA will not approve a suitability petition where the requested change triggers the need for pediatric studies under Pediatric Research Equity Act (PREA) to assess S&E and FDA does not waive the requirement
- Suitability petitions are a race

GDUFA III Suitability Petitions

- FDA and industry agreed to goals on suitability petition reviews
  - –They phase in slowly starting in year two
  - –Provides resources for suitability petition reviews

PREA

- FDA will not approve suitability petitions that need new studies under PREA
  - Impacts, change in active pharmaceutical ingredient (API), new routes and new dosage forms
- Only full PREA waivers (not even deferrals) can be approved
  - The product has no possible use in the pediatric population
  - Existing data covers the new route or dosage form
- Very few post PREA suitability petitions for new dosage forms

Recent Suitability Petitions for Dosage Forms

- FDA-2009-P-0168
  - Cyclobenzaprine Hydrochloride, ER capsule to ER tablet
- FDA-2010-P-0533
  - Metformin Hydrochloride, tablet to powder for oral solution
- FDA-2013-P-1296
  - Acetazolamide, tablet to capsule

The Race

- FDA will not approve an ANDA based on a suitability petition if a b(2) application for the same change is approved first
  - Once the petition is approved, there is a race
- FDA currently continues to accept b(2) applications for the same change after a petition is approved
  - Simultaneous reviews of ANDA based on a SP and b(2) for the same change can occur
- For future consideration
  - What is the public heath benefit of the race? Does it deter the generic industry from optimal use of the suitability petition process?
  - Is there are more optimal balance?

Conclusion

- To maximize J, we should make the suitability petition process work better
- GDUFA III is a start but there are other parts of the system that can affect how broadly we can use suitability petitions
- Timelines for evaluation of suitability petitions will expose other challenges in their use


FDA
U.S. FOOD & DRUG
ADMINISTRATION