

Response to GDUFA Implementation

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Benefits

- Implementation of Complete Response Letters
- Issuance of multiple guidances providing greater clarity on Agency expectations of incoming ANDAs and PAS submissions
- More timely response on new post approval submissions already being seen
- Movement regarding the “backlog” of post approval submissions is apparent
- Early Complete Assessment reviews of DMFs
- Anticipation of year 3 metrics to add greater certainty to review timing.

Challenges

- Timing of recent guidances has been rather close to the start of Cohort year 3; unknown enforcement timing
- Spirit of GDUFA is for increased transparency and predictability in review process/timing but:
 - Current communications with Agency PMs has offered less information on status than pre-GDUFA
 - Controlled Correspondence Guidance expressly states status checks are not permitted – presumed even for those that are not addressed within the goal dates.
 - Would an Agency response of – “remains under review” be permitted as an action meeting goal date definitions for complicated Controlled Correspondences or those requiring policy development?
 - Pre-ANDA Meeting requests require timely Agency feedback but are excluded from Controlled Correspondence metrics
 - The recently issued Controlled Correspondence guidance serves to remove/exclude many topics that would have been considered Controlled Correspondences at the time of GDUFA discussions.

Questions raised by OGD

- Are there comments on the five draft guidances?
 - Comments have been/will be submitted via GPhA and/or the docket
- Are there GDUFA implementation issues related to the five guidances that have not been addressed?
 - Those submissions that do not fall within the GDUFA timing metric are not held to any given limitations and thereby could fall into “limbo”.
 - When are the GDUFA guidances targeted to become official and be consistently enforced for all applications
 - Removal of too many topics from the Controlled Correspondence Guidance without indication of process or limitations on those excluded

Questions raised by OGD

- What other GDUFA implementation topics need the development of guidance?
 - Define a process and timing for those topics which have been excluded from the Controlled Correspondence Guidance where possible.

Questions Raised by OGD

- Are there other topics or issues related to generic drug development ...that need development of guidance?
 - Inactive Ingredients Database (IID)
 - Accuracy/Completeness of current database
 - May serve to decrease the # of requests related to inactive ingredients
 - Single dose vs Maximum Daily Dose
 - Dosage form interchangeability for IID justification
 - e.g. Buccal vs. sublingual vs transmucosal
 - topical vs transdermal
 - Complex Drug Products (LARs, Rings)
 - Combination drug products (drug and device; kits)
 - Abuse Deterrent Requirements
- Section 1133 of FDASIA
 - Aimed to extend first PIV applicant's period to obtain Tentative Approval without forfeiting eligibility of exclusivity
 - Due to language of law, there is ambiguity regarding the length of this period - 30, 36 or 40 months?