PROPOSED USER FEE PERFORMANCE METRICS

Application Median Review Times* (review times include both pending applications and new submissions)

*Median review time is irrespective of whether the application is blocked from approval as a result of a patent, exclusivity, 30 month stay, or court order

- Median review times of all applications reduced to at least 20 months within one year of effective date
- Median review times of all applications reduced to at least 16 months within two years of effective date
- Median review times of all applications reduced to at least 12 months within three years of effective date and each year thereafter

Prior Approval Supplement Median Review Times (review times include both pending applications and new submissions)

- Median review times of all supplements reduced to at least 12 months within one year of effective date
- Median review times of all supplements reduced to at least 9 months within two years of effective date
- Median review times of all supplements reduced to at least 6 months within three years of effective date and each year thereafter

Inspections

- All domestic and foreign establishments GMP inspected at least once every two years, starting within two years of effective date
- Foreign registered establishments will not experience import delays except for good cause shown. If an import hold or delay is imposed at the border involving an FDA registered establishment's product, FDA must provide notice of the concerns within 24 hours of imposing an import delay or hold and shall take action to resolve ore request further information within 48 hours of receipt of additional information.
- Foreign registered establishments will be permitted to import more than one shipment at a time to receive the forecasted quantities needed prior to approval under FDA's Pre-Launch Activities Import Request
- Inspector team to provide inspection report to headquarters within two weeks of inspection
- Office of Compliance must review inspection report and provide any feedback within two weeks of receipt
- Office of Compliance must review 483 responses, issue close out action/Establishment Inspection Report and update Office of Compliance internal inspection status database within two weeks of receipt of 483 responses or seek additional information within two weeks following receipt of reply
- FDA shall expedite and prioritize inspections for facilities associated with an application that is otherwise approvable except for an outstanding inspection. Such inspection must occur within 30 days of date ANDA is expected to become otherwise approvable.
- When an applicant adds a new site of manufacture or any other change requiring an inspection including those identified in FDA's Post Approval Changes Guidance, including first time site registrants, FDA shall expedite and prioritize such inspections to occur within 30 days of receipt of notice of such change by the applicant

Controlled Correspondence Response, Notification of Issues Identified during the Review and Planned Review Timelines

- Median complete response time to controlled correspondence request for feedback reduced to at least 120 days within one year of effective date
- Median complete response time to controlled correspondence request for feedback reduced to at least 90 days within two years of effective date
- Median complete response time to controlled correspondence request for feedback reduced to at least 60 days within three years of effective date and each year thereafter
- For at least 90% of all applications, FDA will report substantive review issues identified that could impact approval (or lack thereof) to the applicant within 10 business days following the date that is six months after ANDA submission and again every three months thereafter until approval/disapproval by telephone, conference, facsimile, secure email, or other expedient means and also inform the applicant of the planned timeline to complete review, including a date by which the applicant will receive feedback from the review division regarding open matters, including, for example, labeling, food studies, etc.

Guidance Development and Outstanding Regulation Development

- Within two years following effective date, FDA will develop guidances on the following topics: Specificity regarding post approval changes that, based on a risk based approach, do not require supplement approval
  Within two years following effective date, FDA shall publish proposed regulations interpreting the 180 day forfeiture provisions provided in 21 USC 355(j)(5)(D)(i) and finalize such regulations within three years following effective date
- Within 30 days of effective date, FDA shall update its agency policy and guidance documents to include biennial inspection requirement for foreign establishments

Formal Meetings

- Schedule and conduct at least 90% of Type A meeting requests (as defined in PDUFA plus meetings requested following issuance of FDA feedback that is different from standard practice or previous agency guidance/recommendation) within 60 days of request within two years of effective date
- Schedule and conduct at least 90% of Type B meeting requests (as defined in PDUFA plus meetings requested following issuance of FDA feedback that is different from standard practice or previous agency guidance/recommendation) within 60 days of request within two years of effective date

FDA Staffing and Resources

- Increase reviewer to application ratio
- Hire additional inspectors, reviewers, and develop and implement training to achieve application median review time metrics and to inspect all domestic and foreign establishments at least once every two years.

Establishment Registration Database

- Develop database of all FDA registered establishments and provide registration online verification lookup within 6 months of effective date, including a registration lookup for the public, a more detailed internal database for FDA's CDER and an internal database for use at US ports of entry for imported product

Annual Congressional Report

Within six months of the one year anniversary of the effective date and annually thereafter, FDA to report the following to Congress:

- Median review times of all applications (including those applications that are pending at the time of effective date) broken down by year
- Median review times of all supplements (including those supplement that are pending at the time of the effective date) broken down by year
- Number of GMP inspections conducted for domestic establishments during the reporting period, Number of GMP inspections conducted for foreign establishments during the reporting period,
- Number of domestic establishments with biennial inspection incomplete, Number of foreign establishments biennial inspection incomplete
- Number of 483 observations issued to domestic establishments during the reporting period, Number of 483 observations issued to foreign establishments during the reporting period
- Number of other enforcement actions (broken down by type) taken against domestic establishments resulting from GMP inspections during the reporting period, Number of other enforcement actions (broken down by type) taken against foreign establishments resulting from GMP inspections during the reporting period
- Number and amount of Establishment Fees received for the reporting period, broken down by type
- Number and amount of Inspection Fees received for the reporting period, broken down by type
- Number and amount of Application Fees received for the reporting period, broken down by type

- Number of active FDA registered establishments during the reporting period broken down by type, Number of first time registered FDA establishments during the reporting period broken down by type, Number of repeat registered FDA establishments during the reporting period broken down by type
- Median complete response time to controlled correspondence request for feedback during the reporting period
- Percentage of applications that FDA provided timely notification of substantive issues identified
- Average time an application spends in the review queue in active and inactive status, as well as average review times by division
- Average application-to-reviewer ratio for the report period
- Summary of staffing initiatives, including hiring of additional staff (including inspectors and reviewers), and additional training initiatives
- Report on the number of new reviewer and inspector hires
- Summary any other actions taken by FDA during the reporting period to address each of the three core user fee goals:
  - Ensure all players, foreign or domestic, contributing to the U.S. drug system are held to the same quality standard and inspected by the FDA on an biennial basis
  - Expedite the availability of low cost, high quality generic drugs by decreasing the median review time of applications and supplements
  - Enhance the FDA's ability to protect Americans in complex global supply environment by identifying, tracking and requiring the registration of all contributors in each drug product sold in the US