# Improving Generic Competition – Collins Amendment

## Summary

***Improving generic access with set timelines for priority review***. Under this section, FDA would be required to prioritize the review of certain generic applications within eight months (240 days), including for: (1) a drug for where there are not more than three approved competitors; or (2) a drug that is on the drug shortage list. Applicants would be required to submit complete, accurate information regarding facilities involved in manufacturing processes and testing 60 days prior. Under this section, the Secretary could allow for the inspection or re-inspection of a manufacturing facility to be expedited. Finally, FDA would be required to provide generic applicants with status updates, including when an application is awaiting final regulatory action, and publish a list of all drugs approved for which all patents and exclusivity have expired.

***Improve transparency in FDA reporting about the backlog and pending generic applications, priority review applications, and facility inspections***. This section would require that FDA make public on a quarterly basis:

- The number of ANDA applications filed prior to October 1, 2014, that are still pending (this includes applications without goal dates); the average and median time such applications have been pending; the number of such applications that contain a "paragraph iv" certification; and the number of such applications that are subject to priority review.
- The number of ANDAs withdrawn in each reporting month; the tentative approval times for applications approved in the quarter; and the number of applications where FDA has taken action under the new expedited review.

FDA would be required to report annually to the relevant committees:

- The number of applications subject to priority review, including first generics, sole-source, and shortage drugs.
- The time it takes to schedule and complete facility inspections.

***Expediting generic drug development.*** This section would establish a process for improving FDA communication with the sponsor to help accelerate the development and review process in advance of the actual ANDA submission for a drug with three or fewer competitors. At the request of a sponsor, FDA would expedite the review of an application, including through additional communications between FDA and the applicant, as appropriate. This would include meetings, as appropriate, prior to the submission of the application; timely advice and communication to ensure collection of data necessary for approval is as efficient as practicable; for complex products, it would mean assigning a cross-disciplinary project lead to facilitate efficient, collaborative, cross-disciplinary review. A sponsor of drug expedited under this section would report to FDA one year following approval on whether the drug has been marketed.

***List of actively marketed drugs***. This section aims to improve market competition by preventing shortages that result from market exits. As the number of firms in the generic market increases, the price of the product falls, in some cases close to the product's marginal cost. At this point, companies will make the decision to exit, but do not have full information about what other

companies are doing, which can result in drug shortages and price increases if enough companies leave the market at the same time and the remaining companies do not have the ability to supply the entire market. This amendment requires that all drug companies report to the FDA if they plan to remove a product from the market, withdraw an approved application, or transfer such application within 180 days of such an event. This section also requires that FDA maintain a list of generic drugs that have no more than three approved competitor drug products on the market, and designate which drugs are deemed to be medically necessary.

***Suitability petitions***. This section includes a sense of the Senate that FDA fulfill its existing statutory requirement by responding to suitability petitions within 90 days. It would also require FDA to report publicly on a quarterly basis on the number of pending petitions and the number that have been pending longer than 180 days. (Note: a suitability petition is a process used by an applicant to allow for changes from the original reference listed drug (RLD), including a different active ingredient in a combination product in which the other active ingredients match those of the RLD, or for a different route of administration, dosage form, or strength.)

***Inspections***. This section aims to help applicants have a clear timeframe for FDA's response back to them after an applicant has taken corrective action in response to a facility assessment issue identified by FDA. Under this section, in circumstances where an applicant has responded to an inspection finding indicating that necessary changes have been made to the facility, FDA would be required to either re-inspect the facility or make a determination about the applicant's response and whether to approve the application. This would only be for cases where the only obstacle to approval of an application is the inspection finding or where FDA has determined that approving an application is a public health benefit.