interested in any other pertinent information stakeholders would like to share on this topic. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Questions

1. Given the legal requirements in place for applications submitted under section 505(b) and approved under section 505(c) of the FD&C Act, are there regulatory or policy rationales for treating PANDAs differently from other 505(b) applications in certain respects, in particular with respect to the following:

   1.1. Labeling requirements, including requirements related to updating product labeling to reflect certain types of newly acquired safety-related information by submitting a “changes being effected” (CBE–0) supplement to FDA?

   1.2. Patent listing requirements?

   1.3. Eligibility for exclusivity?

   1.4. Certain safety-related requirements, such as the postmarket studies and clinical trials or safety-labeling change requirements in section 505(o) of the FD&C Act or the risk evaluation and mitigation strategies requirements in section 505–1 of the FD&C Act?

   In responding to the questions above, please provide a specific rationale for treating these applications differently.

2. To the extent that PANDA holders are expected to make changes to their current practices, what factors should FDA consider in determining a reasonable amount of time for PANDA holders to make such changes to their practices?

3. Are there additional steps FDA should take to highlight for PANDA holders that their “abbreviated new drug application” is a PANDA, i.e., that it is a 505(b) application?

4. Are there additional steps FDA should take beyond posting the list on the Orange Book website to aid other interested persons in identifying PANDAs?

5. Are modifications needed to the list of PANDAs posted on the Orange Book website for accuracy? For example, are some PANDAs missing from the list?

6. Are there other issues FDA should consider in assessing the regulatory framework for PANDAs under the FD&C Act? Please provide specific examples and explain FDA’s authority to address these issues.