ASRS American Society of Retina Specialists

American Academy of Ophthalmology
The Eye M.D. Association

Summary Points

FDA Draft Guidance Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application

February 2015
Docket No. FDA-2014-D-1525

- In February 2015, FDA released draft guidance outlining how the agency intends to regulate compounding and repackaging of biological products, including bevacizumab (Avastin), at compounding facilities.
- The draft guidance will allow for compounding facilities to continue to repackage bevacizumab for ophthalmic use.
- While the draft guidance recognizes the importance of repackaged products to ophthalmology, it includes some restrictions that would, in effect, eliminate the ability of an ophthalmologist to use bevacizumab.
- Proposed "beyond use dates" (BUDs) would make it extremely difficult for ophthalmologists to order and store bevacizumab for office use:
    - For 503A "traditional compounders," proposed BUDs are as follows:
        - Not longer than 4 hours, or is equal to the time within which the opened product is to be used as specified on the approved labeling, whichever is shorter; or
        - Up to 24 hours if microbial challenge studies performed on the formulation of the repackaged biological product in the type of container in which it will be packaged demonstrate that microbial growth will not progress to an unacceptable level within the period of the BUD.
        - Bevacizumab from 503A facilities will still need a patient-specific prescription.
    - For 503B "outsourcing facilities," proposed BUDs are as follows:
        - Not longer than 4 hours, or is equal to the time within which the opened product is to be used as specified on the approved labeling, whichever is shorter; or
        - Up to 24 hours if microbial challenge studies performed on the formulation of the repackaged biological product in the type of container in which it will be packaged demonstrate that microbial growth will not progress to an unacceptable level within the period of the BUD; or
        - No longer than 5 days or the expiration date of the product being repackaged, whichever is shorter, provided that the outsourcing facility conducts adequate compatibility studies on the container-closure system of the repackaged product to demonstrate compatibility and ensure product integrity.
        - Bevacizumab from 503B facilities can be repackaged for office use.

The draft guidance states the BUD timeframes begin when the container of the original biological product to be packaged is opened.

- The proposed BUDs do not allow adequate time for sterility testing.

- Please tell the FDA how the proposed BUDs will affect your practice and patients, and why longer BUDs for bevacizumab are necessary.

Written comments are due by May 20, 2015 and can be submitted at www.regulations.gov.