

effect, the products are not in the same product class for purposes of section 7002(e)(2) of the Affordable Care Act.

Q. II.3: What type of marketing application should be submitted for a proposed antibody–drug conjugate? [New]

A. II.3 (Proposed Answer): As described in further detail below, a BLA should be submitted for a proposed monoclonal antibody that is linked to a drug (antibody–drug conjugate). The FDA considers an antibody–drug conjugate to be a combination product composed of a biological product constituent part and a drug constituent part (see 21 CFR 3.2(e)(1); 70 FR 49848, 49857–49858; August 25, 2005).

CDER is the FDA center assigned to regulate antibody–drug conjugates, irrespective of whether the biological product constituent part or the drug constituent part is determined to have the primary mode of action (see section 503(g) of the FD&C Act; see, e.g., Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research [June 30, 2003], available at <http://www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm136265.htm>; Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research [October 31, 1991], available at <http://www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm121179.htm>).

To enhance regulatory clarity and promote consistency, CDER considered several factors to determine the appropriate marketing application type for antibody–drug conjugates, including the relative significance of the safety and effectiveness questions raised by the constituent parts, particularly the highly specific molecular targeting by the antibody to a cell type, cellular compartment, or other marker at the site of action (as distinguished from mere alteration of systemic pharmacokinetics).

In light of such factors, CDER considers submission of a BLA under section 351 of the PHS Act to provide the more appropriate application type for antibody–drug conjugates.

Sponsors seeking to submit a BLA for a proposed antibody–drug conjugate should contact CDER’s Office of New Drugs at 301-796-0700 for further information.

3.12.4 Exclusivity

Q. III.1: Can an applicant include in its 351(a) BLA submission a request for reference product exclusivity under section 351(k)(7) of the PHS Act?

A. III.1 (Proposed Answer): Yes. The FDA is continuing to review the reference product exclusivity provisions of section 351(k)(7)