definitions of "polypeptide" in the scientific literature. Some are broad (e.g., polypeptide means any amino acid polymer) while others are more narrow (e.g., polypeptide means any amino acid polymer composed of fewer than 100 amino acids). The FDA believes that a narrow definition of the polypeptide is most appropriate in this context because, among other reasons, this avoids describing an exception to the category of protein using a term that relates to a larger class of molecules. Therefore, the FDA interprets the statutory exclusion for "chemically synthesized polypeptide" to mean any molecule that is made entirely by chemical synthesis and that is composed of up to 99 amino acids. Such molecules will be regulated as drugs under the FD&C Act unless the chemically synthesized polypeptide otherwise meets the statutory definition of a "biological product."

There may be additional considerations for proposed products that are combination products or meet the statutory definition of both a "device" and a "biological product." We encourage prospective sponsors to contact the FDA for further information on a product-specific basis.

Q. II.2: How is "product class" defined for purposes of determining whether an application for a biological product may be submitted under section 505 of the FD&C Act during the transition period?

A. II.2: For purposes of section 7002(e)(2) of the Affordable Care Act, a proposed biological product will be considered to be in the same "product class" as a protein product previously approved under section 505 of the FD&C Act on or before March 23, 2010, if both products are homologous to the same gene-coded sequence (e.g., the INS gene for insulin and insulin glargine) with allowance for additional novel flanking sequences (including sequences from other genes). Products with discrete changes in gene-coded sequence or discrete changes in post-translational modifications may be in the same product class as the previously approved product even if the result may be a change in product pharmacokinetics.

For naturally derived protein products that do not have identified sequences linked to specific genes and that were approved under section 505 of the FD&C Act on or before March 23, 2010, a proposed biological product is in the same product class as the naturally derived protein product if both products share a primary biological activity (e.g., the four-number Enzyme Commission code for enzyme activity).

However, for any protein product (whether naturally derived or otherwise), if the difference between the proposed product and the protein product previously approved under section 505 of the FD&C Act alters a biological target or