The presentation will include our experience with coagulation-based recombinant proteins, specifically those recombinant proteins involving genetically engineered/optimized coding sequences. Recombinant therapeutics may prove advantageous over human-plasma-derived products due to decreased prion and viral contamination. The optimized and other unnatural sequences may have a significant impact on the expression, half-life, localization and physiologic function of these therapeutic proteins. The presentation will highlight possible effects of one or more synonymous or non-synonymous mutations on a broad spectrum of recombinant therapeutic proteins.

Biography
Chava Kimchi-Sarfaty is a CBER representative in the FDA Pharmacogenomics group charged with writing a guidance document for the role of pharmacogenomics in industry. She is also a member of the Genomics Activity Group in the Office of Blood Research and Review. She serves on the FDA Chief Scientist Committee.
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