Biosimilars are approved based on data showing that they are highly similar to a product that's already FDA approved and have no clinically meaningful differences in safety and efficacy. In a phase 3 clinical trial, 705 patients were randomly assigned to receive monthly injections of ranibizumab-nuna or ranibizumab for 48 weeks. An interim analysis showed that the 2 drugs were equivalent in measures of best-corrected visual acuity at 8 weeks and in macular thickness at 4 weeks. The study’s authors wrote that they plan to publish longer-term data.

FDA officials noted that ranibizumab-nuna can cause serious adverse effects such as infection inside the eye, retinal detachment, increased intraocular pressure, and thromboembolic events. Common adverse events include conjunctival hemorrhage, eye pain, and vitreous floaters.

Progress in FDA’s Review of Millions of Tobacco Products

In early September 2020, the FDA faced a 1-year deadline to review more than 6.5 million tobacco products, some that already were on the market but hadn’t been through the FDA review process. Thousands of applications representing those products—most are electronic nicotine delivery systems (ENDS)—have now been reviewed, and the agency has taken action on about 93% of them.

The reviews stem from the “deeming rule” that went into effect in August 2016 as a way to help implement the Tobacco Control Act of 2009, which gave the FDA authority to regulate tobacco products. The law requires new tobacco product marketing to be “appropriate for the protection of public health” in terms of its effects on youths’ tobacco use and whether new products might help adults to stop smoking combustible cigarettes. The deeming rule then extended the same regulatory requirements for cigarettes and smokeless tobacco that were established in the 2009 law to e-cigarettes, ENDS, cigars, pipe tobacco, nicotine gels, hookah tobacco, and any future tobacco products.

Among the actions taken since September 2020, FDA officials notified Texas-based vaping product seller JD Nova Group LLC that applications for marketing approval covering 4.5 million of its products haven’t met filing requirements. The agency also issued marketing denials for more than 946,000 flavored ENDS products.

“[W]e know that flavored tobacco products are very appealing to young people,” acting FDA Commissioner Janet Woodcock, MD, and Mitch Zeller, JD, director of the FDA’s Center for Tobacco Products, said in a statement. “[A]ssessing the impact of potential or actual youth use is a critical factor in our determination as to whether the statutory standard for marketing is met.” —Rebecca Voelker, MSJ

Note: Source references are available through embedded hyperlinks in the article text online.