Summary of Public Comments and Explanation of Changes to the MDUFA IV Recommendations

On October 25, 2016, FDA posted on its website the draft recommendations for reauthorizing the Medical Device User Fee Amendments (MDUFA). On November 2, 2016, FDA held a public meeting to discuss the draft recommendations. The public comment period ended on November 28, 2016. FDA received 17 written comments to the public docket, in addition to the comments expressed at the public meeting. Most of the comments supported the draft recommendations. FDA is providing the following explanations regarding changes to the draft recommendations, which are reflected in the final recommendations.

Enhanced Use of Consensus Standards

In section IV.D of the Commitment Letter (Enhanced Use of Consensus Standards), FDA made technical edits to clarify that under the Accreditation Scheme for Conformity Assessment program, accrediting bodies will accredit test laboratories, rather than having accrediting bodies accredit certifying bodies that would certify test labs. Removing reference to certifying bodies clarifies how the scheme will operate and does not change the commitment to set up a program through which third parties accredit test labs and FDA generally accepts declarations of conformity from those test labs without requiring additional information regarding standards conformance during premarket review.

Real World Evidence

In section IV.H of the Commitment Letter (Real World Evidence (RWE)), FDA added language specifying that the National Evaluation System for health Technology (NEST) governing board will include, but not be limited to, representation from patient organizations. This addition was made in response to several comments received during the public comment period—including comments voiced at the November 2, 2016, MDUFA public meeting—that because the Commitment Letter specifies the extent of industry's representation on the governing board, it should also specify that patient organizations will be appropriately represented on the governing board. This addition does not change any aspect of how the NEST Coordinating Center or governing board will operate because FDA, industry, and patient organizations have long understood that the governing board will include representatives from patient organizations.

Small Business Fees

FDA received comments regarding the establishment registration fee, which is assessed on all device manufacturers annually. Some commenters requested a waiver of this fee for small businesses with modest annual revenues.

Although businesses that meet the definition of a "small business" are eligible for certain reduced or waived premarket submission user fees, the statute does not provide for a reduced or waived establishment registration fee for any business, nor did the MDUFA IV draft recommendations include any such reduction or waiver. The fee amounts and fee structure (the schedule of fees paid for certain submissions or activities), including the annual establishment registration fee, are designed to balance the need for stable and reliable funding for FDA with the need to reduce barriers to market entry and encourage innovation. Fees support FDA's process for the review of device premarket submissions by providing resources to, among other things, hire staff with needed expertise, modernize information management systems, facilitate additional interactions between FDA and applicants, and provide more

guidance to prospective applicants. Such activities ultimately allow FDA to review medical devices for safety and effectiveness more rapidly, predictably, consistently, and transparently. This benefits sponsors and manufacturers of all sizes, the health care community, and (most importantly) patients. For these reasons, the MDUFA IV final recommendations do not include any changes to the establishment registration fee structure.