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FDA In Brief

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FDA In Brief: FDA announces temporary streamlined program to help manufacturers of human cell, tissue, and cellular and tissue-based products – including stem cell treatments – understand the appropriate regulatory pathways for their products

"When the FDA announced its comprehensive regenerative medicine policy framework in November 2017, the agency provided recommendations to facilitate the development of regenerative medicine products, including cellular therapies. Additionally, to give product developers time to determine if their products required premarket review and approval, we also announced that we generally intend to exercise enforcement discretion for 36 months from November 2017 for human cells, tissues, and cellular and tissue based products with regard to the premarket approval requirements, when the use of the product does not raise reported safety concerns or potential significant safety concerns," said Acting FDA Commissioner Ned Sharpless, M.D. "However, we're more than halfway through the enforcement discretion period, and the pace of progress of those offering these human cells, tissues, and cellular and tissue-based products, including stem cell treatments, to come into compliance with the requirements has been slower than expected. It's possible some stakeholders have questions about the requirements or length of the process. Therefore, to help stakeholders that may have questions about how their products are regulated, we are putting into place a temporary program to help manufacturers and those who market products to physicians or patients, quickly obtain an informal, non-binding assessment from the FDA about how their products are regulated. We remain firmly committed to advancing an efficient path for the safe and effective development of regenerative medicine products and to help foster beneficial new innovations. However, we also know there are many cases of companies making unsubstantiated claims about the potential for human cells, tissues, and cellular and tissue-based products to prevent, treat or

cure serious diseases, and in those cases, we are committed to taking action and protecting patients."

The U.S. Food and Drug Administration is announcing a temporary program called the TRG Rapid Inquiry Program (TRIP), which will operate as part of FDA's Tissue Reference Group. The program will assist manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), including those stakeholders that market HCT/Ps to health care professionals and/or patients, obtain a rapid, preliminary, informal, non-binding assessment from the FDA regarding how specific HCT/Ps are regulated. The agency intends to respond to inquiries that contain sufficient detail for evaluation within three days of receipt, as resources permit. The program will be available until December 31, 2019.

The FDA currently provides regulated industry several ways to obtain information about the regulatory status of an HCT/P including, for example, whether an HCT/P meets the criteria in FDA regulations (21 CFR 1271.10(a)) for regulation solely under Section 361 of the Public Health Service Act and 21 CFR 1271:

- FDA's Tissue Reference Group (TRG) provides product manufacturers and sponsors with an informal process through which they may obtain an Agency recommendation regarding the application of the criteria in 21 CFR 1271.10(a) to their HCT/P for a given indication for use.

- The Request for Designation (RFD) process may be used to obtain a formal Agency decision regarding the regulatory identity or classification of an HCT/P from FDA's Office of Combination Products. Information on how to write an RFD is posted on the agency's website.

- The Pre-RFD process is used to obtain preliminary feedback from OCP on the classification of an HCT/P. Information on this process may be found on the agency's website.

For more information:

FDA: TRG Rapid Inquiry Program (TRIP)
FDA: Comprehensive Regenerative Medicine Policy
FDA: FDA Warns About Stem Cell Claims
FDA: Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products