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FDA to tackle uptick in cell and gene therapy applications with new 'super office'

The new Office of Therapeutic Products is intended to streamline workflow processes

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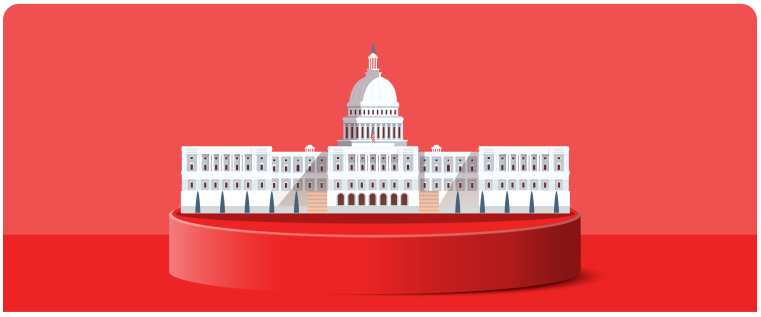

Looking to maximize efficiency in anticipation of an impending flood of cell and gene therapy applications, CBER will morph its Office of Tissues and Advanced Therapies into a new FDA "super office" dubbed the Office of Therapeutic Products.

Wilson Bryan, director of the Office of Tissues and Advanced Therapies (OTAT) at FDA's Center for Biologics Evaluation and Research (CBER), announced the new Office of Therapeutic Products (OTP) at a recent town hall. The virtual town hall was the first in a planned series to answer questions from stakeholders about topics on which OTAT has regulatory oversight, particularly when it comes to addressing CMC-related issues, which was the focus of the event. The rapid proliferation of new modality therapies with unique CMC issues, which has ramped up FDA's need to provide guidance as well as to review more submissions, is one driver behind the creation of OTP.

A Sept. 28 *Federal Register* notice stated that CBER is "facing scientific, medical and regulatory challenges that require changes to its structure."

Those challenges include a growing workload. In congressional testimony ahead of PDUFA VII reauthorization, CBER Director Peter Marks said, "FDA has experienced exponential growth in cellular and gene therapy submissions over the past 7 years," including "an 85% increase in original IND receipts, a 139% increase in IND amendment receipts, and a 158% increase in formal meeting requests."

CBER expects its workload, especially from cell and gene therapies, to continue to grow.

The proposal for the new super office, which was approved by HHS on Aug. 8 and came into effect on Sept. 16, is receiving funding through PDUFA VII, which was reauthorized last week. Under the PDUFA VII commitment letter, CBER will hire 132 new staff members in FY23 and 48 in FY24.

The super office structure is intended to improve alignment between functions, increase review capabilities and enhance staff expertise on new cell and gene therapies. CBER spokesperson Paul Richards told BioCentury the structure achieves this by creating "multiple office-level organizational components within its substructure organization as direct reports."

"The structure creates the span and layers needed within an organization, such as OTAT, to grow the total number of divisions, branches, staffs, and teams as needed," said Richards.

OTP breaks down OTAT into six suboffices, including a dedicated suboffice of gene therapy CMC, as well as 14 divisions and 32 branches.

The divisions create additional supervisory positions that will not only help address the increased workload, but also provide advancement opportunities to facilitate the recruitment and retention of highly qualified staff, a longstanding challenge at the agency.

The super office structure is also meant to offer flexibility and capacity for future growth in staff and workload, thereby avoiding the need for frequent reorganizations.

OTP will oversee the growth of the agency's Regenerative Medicine Advance Therapy program to advance the field and support the next generation of cell and gene therapies.

"This restructuring will enhance OTP's and CBER's capabilities to focus on our commitments to advance drug development and fulfill the FDA's mission of protecting and promoting public health," Bryan said at the townhall.

The transition will take place over the next several months, with the new organization structure planned to take effect in mid-February, Richards told BioCentury.

There are no changes to the regulatory review process as a result of this reorganization, and the agency expects no impacts to pending applications, he said.

Richards also noted that CBER is currently in the process of filling key positions within the organization.

Ahead of the formal realignment of teams, CBER intends to provide additional information related to any specific changes that may affect sponsors' interactions with OTAT staff, including key points of contact.

"Until then, sponsors can continue to navigate OTAT as they do today, directing questions related to a regulatory submission that has been received by CBER to their assigned regulatory project manager," said Richards.

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