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21 U.S. Code § 356-2

Accelerated approval Council

(1) In general

Not later than 1 year after December 29, 2022, the Secretary shall establish an intra-agency coordinating council (referred to in this subsection as the "Council") within the Food and Drug Administration to ensure the consistent and appropriate use of accelerated approval across the Food and Drug Administration, pursuant to section 356(c) of this title.

(2) Membership

The members of the Council shall consist of the following senior officials, or a designee of such official, from the Food and Drug Administration and relevant Centers:

(A) The Director of the Center for Drug Evaluation and Research.

(B) The Director of the Center for Biologics Evaluation and Research.

(C) The Director of the Oncology Center of Excellence.

(D) The Director of the Office of New Drugs.

(E) The Director of the Office of Orphan Products Development.

(F) The Director of the Office of Tissues and Advanced Therapies.

(G) The Director of the Office of Medical Policy.

(H) At least 3 directors of review divisions or offices overseeing products approved under accelerated approval, including at least one director within the Office of Neuroscience.