Bill: **To amend the Federal Food, Drug and Cosmetic Act to establish additional authorities of the Food and Drug Administration regarding the conduct of pediatric investigations of molecularly targeted drugs to treat cancer.** *In this document, the term "drug" shall refer to both drugs and biologics.*	
Section 1: Short Title	RACE for Children Act of 2021 *[name to be changed]*
Section 2: Research into Pediatric uses of Drugs; Additional Authorities of Food and Drug Administration Regarding Molecularly Targeted Cancer Drugs	
Subsection 2(a): In General – Authority Regarding Investigation of Combination of Active Ingredients	When the requirement for a pediatric investigation is triggered by a sponsor's NDA or BLA for a new active ingredient, FDA has two options. First, it can require a pediatric investigation of the application drug/biologic (as under current law). Second, as an alternative, FDA can require a pediatric investigation of the application drug/biologic in combination with an active ingredient of a drug/biologic in that sponsor's pipeline for which an IND is in effect, or in combination with an active ingredient of an already approved drug/biologic (the new alternative under the legislation). For the first option, the purpose of the pediatric investigation is to inform potential pediatric labeling of the application drug/biologic (as in current law). For the second option, the purpose of the pediatric investigation of the combination is to assist in determining the relevance of its molecular target to the growth or progression of a pediatric cancer (new under the legislation). For either option, the reports on an investigation must include the results of the relevant preclinical studies.
Paragraph 2(a)(2): Clarifying Applicability of Certain Provisions	Technical corrections to clarify that the provisions of the Pediatric Research Equity Act apply to pediatric investigations in the same way as they apply to pediatric assessments.

Subsection 2(b): Requirement Regarding Conduct or Support of Pediatric Assessments and Investigations [and Written Requests]	Has the effect that a sponsor of a pediatric investigation or assessment must provide timely, 100% financial support for the assessment or investigation, and for the relevant preclinical studies. References 21 CFR Section 314.108, which provides guidance as to how a sponsor demonstrates financial support.
Subsection 2(c): Authority Regarding Preclinical Studies	Provides FDA with new authority regarding the submission of any IND for a drug/biologic. Specifically, FDA can require, at its discretion and as a condition of allowing the IND to go into effect, that preclinical studies of the drug/biologic be conducted to in order to assist in determining the relevance of its molecular target to the growth or progression of a pediatric cancer.
Subsection 2(d): Applicability	Fully implements the provisions of this bill upon [3 years] from enactment.