

## **Candidate Pediatric Molecular Target List**

Pursuant to section 505B(m)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the table labeled “automatic waivers” lists the “molecular targets of new cancer drugs and biological products in development for which pediatric cancer study requirements under [section 505B of the FD&C Act] will be automatically waived” (section 505B(m)(1)(B)). All other tables list “molecular targets considered, on the basis of data the Secretary determines to be adequate, to be substantially relevant to the growth or progression of a pediatric cancer, and that may trigger the requirements under [section 505B of the FD&C Act]” (section 505B(m)(1)(A)).

### **A) Automatic Waivers**

Target Symbol
AR
ESR1
ESR2
GnRHR
PSA/PSCA/PSMA