**FOOD AND DRUG ADMINISTRATION (FDA)**
Center for Drug Evaluation and Research (CDER)

***Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting***
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 20, 2018

**DRAFT QUESTIONS**

---

**Topic 1: Target List**

1. **DISCUSSION:** Title V of the FDA Reauthorization Act (FDARA) 2017 assigns FDA to establish, publish and regularly update a list of molecular targets considered on the basis of data the FDA determines to be adequate to be substantially relevant to the growth or progression of pediatric cancers. New drug products directed at these targets may trigger the requirement for pediatric investigations [21 USC 355c(m)(1)(A)]. As well, a list of targets considered "not relevant" [21 USC 355c(m)91)(B)] has been developed. Comment on the process utilized to construct the list, the classification of molecular targets, the factors utilized to designate a target as relevant or non-relevant and indicate your concurrence with the lists as currently presented.

2. **DISCUSSION:** Please comment on the process proposed for formally updating the lists at semi-annual public workshops, the methods for nominating potential future candidate targets, and the required transparency in multi-stakeholder discussions to determine relevance. Comment on additional measures to assure timely discussion of emerging science and its clinical translation which has the potential to expedite drug development to improve the care and outcome of children with cancer.

**FOOD AND DRUG ADMINISTRATION (FDA)**
Center for Drug Evaluation and Research (CDER)

***Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting***
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 20, 2018

**DRAFT QUESTIONS (cont.)**

---

**Topic 2: FDARA Implementation**

1. **DISCUSSION:** Please comment on the proposed additional considerations for which the FDA might engage with industry, clinical investigators, and advocates when making decisions regarding the requirement for pediatric studies of new drug and biologic products based on molecular mechanism of action and their timing.

**FOOD AND DRUG ADMINISTRATION (FDA)**
Center for Drug Evaluation and Research (CDER)

***Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting***
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 20, 2018

**DRAFT QUESTIONS (cont.)**

---

**Topic 3: Mechanisms to Assure Efficiency and to Enhance Global Coordination Through International Collaboration**

1. **DISCUSSION:** Please discuss transparent mechanisms for industry, advocates, and the academic investigator community to communicate and provide input to the FDA for purposes of eliminating unnecessary duplication of clinical trials in rare pediatric cancer populations of same in class agents.

2. **DISCUSSION:** Please comment on process development aimed at enhancing international collaboration between clinical trial networks to facilitate global cancer drug development for children in light of currently non-aligned regulatory requirements.