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 **#NatlCancerForum**
#DrugForum

Updating Labels for Generic Oncology Drugs

March 26, 2019

 NATIONAL
CANCER POLICY
FORUM  Forum on
DRUG DISCOVERY, DEVELOPMENT,
and TRANSLATION

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MEETING OVERVIEW

- Input from the meeting's discussions will inform Project Renewal, an FDA initiative to provide clinicians with accurate labeling information to inform prescribing decisions
- This meeting convenes stakeholders with a broad range of expertise, including:
 - Adult/pediatric oncology
 - Pharmacy
 - Patient advocacy
 - Regulation
 - Statistics/evidence synthesis
 - Guidelines/pathway development
 - Real world evidence
- Meeting participants will examine information sources and evidence standards for labeling updates, including considerations for special populations

Sponsor: Food and Drug Administration

AGENDA

SESSION 1: Background and Overview of the Goals of the Meeting

SESSION 2: Sources of Information

- **First Hour: Small Group Discussions**
- **Second Hour: Report Back to Larger Group**

SESSION 3: Evidentiary Standards for Information Sources

- **First Hour: Small Group Discussions**
- **Second Hour: Report Back to Larger Group**

SESSION 4: Evidence Considerations for Select Populations

- **First Hour: Small Group Discussions**
- **Second Hour: Report Back to Larger Group**

SESSION 5: Advancing Progress on Updating Generic Oncology Drug Labels