# In Closing:

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# An Invitation: Generic Parallel Scientific Advice

**What**: A voluntary pilot program to facilitate discussions between generic drug developers, FDA, and the European Medicines Agency

**Why**: Prospective generic drug applicants can engage in concurrent scientific conversation with both agencies on key issues

**How**: Request a meeting to address specific scientific inquiries around the development of complex generic drug products by emailing a "Request for Parallel Scientific Advice" justification to

EMAinternational@EMA.Europa.EU **and** preANDAhelp@FDA.HHS.gov

# FDA Generic Drug Cluster

- Approvability/ current review challenges
- Regulations and guidances under development
- Data integrity and information sharing
- Data collected under regulations that vary between countries
- Generic drug pipeline challenges
- Accessibility challenges due to emerging global regulatory challenges

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https://www.fda.gov/drugs/generic-drugs/global-generic-drug-affairs

# Generic International Harmonization Efforts

**December 2022**

First draft bioequivalence (BE) guideline under ICH (M13A) on BE for immediate-release solid oral dosage forms

**January 2023**

FDA draft guidance for industry and Federal Register notice to solicit public comments

**May 2023**

FDA webinar to help industry with the M13A guidance

**June 2023**

ICH Assembly endorsement of a second topic to harmonize BE for modified-release products

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