

Pediatric Cluster: Common Commentary

- **Process- Recent addition in 2012**
 - Tool to inform sponsors of products discussed at the Cluster.
 - SOP in place to select products for adding Commentary
 - Discussion points, identifying similarities and/or differences in FDA's and EMA's approach, are summarized in a 1-2 page document that is cleared by FDA and EMA.
 - This document is then sent to the sponsor. Comments sent are NOT binding on either Agency (i.e. they do NOT constitute regulatory advice).