Companion Diagnostics
OBRR Perspective

IVD Roundtable, June 7, 2012

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Definition of a Companion Diagnostic

- “An *IVD companion diagnostic device* … provides information that is essential for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a particular therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product… ”

Excluded from the definition

- “Clinical laboratory tests intended to provide information that is useful to the physician regarding the use of a therapeutic product, but that are not a determining factor in the safe and effective use of the product” are not considered companion diagnostics.

Definition continued

- An IVD companion diagnostic device that supports the safe and effective use of a particular therapeutic may be a novel IVD device (i.e., a new test for a new analyte), a new version of an existing device developed by a different manufacturer, or an existing device that has already been approved or cleared for another purpose.

Uses of a Companion Diagnostic

- Identify patients who are most likely to benefit from a particular therapeutic product
- Identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a particular therapeutic product
- Monitor response to treatment for the purpose of adjusting treatment (e.g., schedule, dose, discontinuation) to achieve improved safety or effectiveness

How FDA handles Companion Diagnostic Submissions

- An IVD companion diagnostic device should be developed and approved or cleared contemporaneously to support the therapeutic product's safe and effective use (e.g., co-development)
  - Limited exceptions
- FDA intends to review each IVD companion diagnostic device submission within the context of, or in conjunction with, its corresponding therapeutic product, and FDA review of the test/therapeutic product pair will be carried out collaboratively among relevant FDA offices.

Labeling

- Drug: “…for use with [class/category] type test…”
  - Device brand, manufacturer, etc, not specified
- Device: typically names the specific drug
  - When appropriate can name the class of drug

Existing Approved /Cleared Devices

If a novel therapeutic product requires the use of a companion diagnostic device to assess a specific analyte and an approved or cleared diagnostic device for that analyte is already available, an additional premarket device application should be submitted to add the new indication for use of the test as a companion diagnostic device. This is because the new use of the diagnostic device with the new therapeutic product could raise new or additional questions of safety and effectiveness.

Relevant products

Regulatory Pathways, as determined by risk, generally unchanged

- CBER regulates viral load tests for HIV as PMAs.
- CBER regulates sequence-based, rules-based HIV drug resistance assays as 510(k)s.
- HIV drug resistance assays with complex interpretation algorithms, including some sequence-based assays are expected to be regulated at the PMA level.
  - Case by case decision, based on risk.
- HLA tests – CBER will regulate all HLA companion diagnostics
  - Contact CBER for regulatory pathway

Recommendations for Companion Diagnostic Submissions

1. Studies should be sized to give power equivalent to studies typically seen for therapeutics.
2. Contact CBER early for pre-IDE/IND support.
3. Have a well developed SAP, with details available early in the pre-IDE/IND phase.