



Patient Medication Information: Pilot Study

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Product Selection Considerations

- Sales volume
- PMI Updates
- Frequently co-prescribed with other medications?
- Some products are gender-specific, or age
- Chronic vs short duration use medication

Product Selection Considerations

- Existing Patient Information
 - Medication Guide (REMS)
 - Medication Guide (no REMS)
 - Patient Information Leaflet (device)
 - Patient Information Leaflet (no device)
 - No Patient Information currently
- Relevance of existing Patient Information to PMI prototype distribution
- Relevance of PMI prototypes to generic products

What Role should FDA play?

- Provide PMI prototypes, including acceptable formats
- Provide “ground rules” for the PMI prototypes
 - 1 page limit (e.g., based on x-minimum type size, y-inch margins, 8 ½ X 11 sheet of paper)
 - Specify any standard Headers for the Prototypes
 - Specify File format in Objectives (WORD vs XML)
 - Provide any considerations for referring patients elsewhere for additional information (such as websites)

What Role should FDA play?

- Consider requiring a common disclaimer statement such as:
 - “This document does not discuss all possible uses of this medicine, or all the possible risks. For more information, contact your doctor or pharmacist.”