

FDA and Prescription Medicine Information

Nancy M. Ostrove, Ph.D.
Director for Risk Communication
Food and Drug Administration

FDA Regulated Information about Prescription Medicines

1. FDA approved (Labeling)
 - for prescribers: prescribing information (PI)
 - for patients, patient information/leaflets, patient package inserts (PPIs), Medication Guides
 - maybe other materials (RiskMAPs/REMS)
2. FDA oversight (promotion)
 - advertisements (in periodicals)
 - promotional labeling (everything else)
 - internet (not classified)

Prescription Medicine Information in the Pharmacy

- Container labels
 - regulation deferred to State Pharmacy Boards
- FDA-approved “Labeling”
 - for prescribers, required for all R_x drugs
 - for patients, required for some but not all
- Labels and labeling defined in law
- Independently supplied information
 - Consumer Medication Information (CMI)

Patient Labeling

1. “Voluntary” PPIs

- not required by law
- may or may not be distributed to patients
- may be used with advertisements

2. PPIs for oral contraceptives & estrogens

- required by regulation to be distributed to patients

3. Medication Guides

- for products that pose a “serious and significant public health concern”
- required by regulation to be distributed to patients

	Medication Guide + Required PPI	Voluntary PPI	Consumer Medication Information
Who drafts?	Manufacturer	Manufacturer	Independent Supplier
Does FDA approve?	Yes	Yes	No
Distribution required at Pharmacy?	Yes	No	No
Reprinted with PI?	Yes	Yes	No

Current Issues

- Public meetings on risk communication and Medication Guides
- Assessment of CMI program
 - has it met the Congressionally mandated goals?
- Citizen Petition requesting “one document solution” for information disseminated at pharmacies