Current Status of Useful Written Prescription Drug Information for Consumers
Text of Presentation Delivered at FDA Public Meeting (Docket No. 03N-0168)

Pharmaceutical Printed Literature Association (PPLA)
July 31, 2003, in Washington, D.C.
Delivered by Peter G. Mayberry, Executive Director, PPLA

1. PPLA Overview:

- Not-for-profit association chartered in 2001
- Serves as the voice of pharmaceutical printed package information manufacturers and material and technology suppliers
- Provides a forum for members to promote and improve delivery of information for the benefit and protection of patients
- Includes providers of package inserts, patient physician inserts, outserts, MedGuides, folding cartons, labels and other printed components for the pharmaceutical industry, as well as material and equipment suppliers used in the production of pharmaceutical printed literature
- –PPLA members are responsible for printing the majority of package inserts distributed in the United States today
- For more information please visit: www.pplaonline.org

2. Current FDA-Approved Copy Accompanying Rx Drug Products

Generally speaking, PPLA Members print three types of literature containing FDA-approved copy:

– ***Package Inserts (PIs)*** intended to ensure that physicians and dispensers have the information needed to counsel consumers and dispense Rx products properly

- PIs are not intended for the general public

– ***Patient Package Inserts (PPIs)*** intended to enable patients to use the medicine properly, receive the maximum benefit, and avoid harm

- PPIs are intended for the general public
- PPIs currently accompany a very small number of drug products, and are used exclusively at the manufacturer's discretion

– ***Medication Guides (MedGuides)*** accompany a very small number of Rx drugs that pose "a serious or significant public health concern"

- MedGuides are intended for the general public

03N-0168 TS 4

3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 Goal?

- FDA should be proactive in ensuring that "useful" information is supplied to consumers, as opposed to reactively trying to assess whether useful information is being dispensed, especially critical in post-PDUFA environment
- Printed literature is "fundamental to good pharmacovigilance programs" (Mark McClellan, April 11, 2003)

4. FDA's Role in Meeting Action Plan Goals

- Private sector initiatives have failed

  –% of printed literature dispensed to consumers that contains useful patient information: "...only about 50 percent" (National Association of Boards of Pharmacy, 2002)

  –Multiple vendors supplying pharmacies with non-FDA approved copy means wide disparity of information

  –Lack of Federal oversight means inconsistency

5. FDA's Role in Meeting Action Plan Goals

- FDA-approved copy intended for consumers should accompany every prescription dispensed
- Information should be drawn from PIs – which are already available for all Rx drug products – but should be in a PPI or MedGuide format
- Information should incorporate the six elements of "usefulness" from the Keystone Action Plan ("scientifically accurate," "unbiased in tone and content," etc.)
- At a minimum, copy should be in 10-point type and should include information regarding:
  - Indications and usage
  - Contraindications
  - Warnings & precautions
  - Adverse reactions
  - Overdoses
  - Dosage and administration

6. FDA's Role in Meeting Action Plan Goals

- Printed information should be prepared by the manufacturer and sent to dispensing points with all Rx products

  –Only means FDA has of insuring approved information is available to consumers
  –Technologically and economically feasible approach

7. Photo: Medication Bottle w/outsert (unopened)

8. Photo: Medication Bottle w/outsert (opened)

9. Photo: Patient Package Insert

10. Photo: Combination Package Insert/Patient Package Insert

11. Benefits

- Ensures Action Plan goals are met
- Improves consumer safety
- Ensures accuracy, consistency, and usefulness of information
- Can be implemented rapidly, and CGMP-based control procedures for approved copy management are already in place
- Product designs, package configurations and FDA-approved copy (PIs) exist which enable the delivery of this information to consumers throughout the supply chain
- Modest incremental cost would increase patient safety and improve compliance with pharmaceutical regimens

12. Next Steps

The PPLA welcomes the opportunity to work with FDA to ensure that useful information is dispensed with all Rx drug products.