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Use of Medication Guides to Distribute Drug Risk Information to Patients: FDA Public Hearing

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(GPhA)

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- Compliance with Medication Guide Requirements
 - Experience with Electronic Forms of Medication Guides
 - Pharmacy Instructions for Dispensing Medication Guides
 - Proposal of Standardized Language and/or a Uniform Symbol
 - Unit-of-Use Packaging
 - Class Specific Medication Guides
 - Summary

Compliance with Medication Guide Requirements

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- Dispensing statement provided on container label such as “**PHARMACIST**: Provide Medication Guide to patient with medication.”
- Engineering challenges in designing, folding and affixing increasing amounts of information to containers.
- Difficulty in assuring patient receipt; use of technology may enhance compliance (i.e., paperless labeling).

- Medication Guides typically not provided as electronic files.
 - Firms advised by FDA that it was not acceptable because there was no way to assure that ALL pharmacies could access, view, print and distribute.
- Strong interest in the generic industry to promote the use of technology and work towards electronic distribution of Medication Guides.
 - One central database needed – consider DailyMed or the National Library of Medicine websites? Follow path of paperless labeling initiative.

- Dispensing statement provided on container label such as “**PHARMACIST:** Provide Medication Guide to patient with medication.”
 - Objective is to provide one Medication Guide for each prescription dispensed.
 - Issue Medication Guides as perforated or tear-away pages.
 - Supply additional Medication Guides to wholesalers and other members of the supply chain.
 - Ability to supply pharmacy with additional Medication Guides by contacting manufacturer/third party supplier.

Proposal of Standardized Language and/or a Uniform Symbol

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- A uniform symbol on the bottle label could be a space efficient means of alerting the pharmacist to a Medication Guide requirement.
 - No specific recommendations of a symbol at this time.
- The majority of the generic industry is currently using a dispensing statement on container label such as “**PHARMACIST**: Provide Medication Guide to patient with medication.”

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- Companies have worked hard to become more creative in fitting information on bottles, but there are practical limits to engineering abilities. Practicality calls for an exploration of available technologies.
 - **Advantages**
 - Medication Guide is already attached to the bottle during the manufacturing process, thus increasing assurance that information is made available to the patient.
 - Little or no repackaging by pharmacist.

- **Disadvantages**

- Impractical for all products.
 - Medication Guides cannot be affixed to all container types (i.e., syringes).
 - Hospitals, nursing facilities, etc. repackage into their own dispensing units. More efficient (time, cost, storage) to purchase in bulk containers.
 - “As needed” dosages supplied as a unit-of-use may provide patients with too much or not enough medication. Multiple dosing regimens difficult to dispense (i.e., bupropion).
- Will result in increased cost to patients.

- **Advantages**

- FDA and industry can collaborate to create standardized text and work in a consortium to provide information to pharmacies. Already successfully implemented with NSAIDs and antidepressants.
- Availability and distribution of Medication Guides can be managed to ensure pharmacies receive or have access to the necessary information.
- Provide even greater advantages as an electronic version.

- **Disadvantages**

- Potential variations of data and side effects within each drug class – could cause some confusion for patients.

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- Concerned with patient safety, education and communication.
 - As Medication Guides become more prominent, industry is facing ever increasing engineering complications.
 - Willing to collaborate to find a system that satisfies all stakeholders.
 - Focus on available technologies; an electronic system or FDA/NLM database that can provide most up-to-date information to pharmacists and patients.