

# Medication Guides

## for Certain Prescription Products

**F**DA wants you to know the importance of reading Medication Guides—paper handouts that come with many prescription medicines. The Agency also wants input on how to make these guides as useful and user-friendly as possible.

“The information in a Medication Guide is very important when it comes to getting the most benefit for your health from a medicine,” says Paul Seligman, M.D., M.P.H., Associate Director for Safety Policy and Communication in FDA’s Center for Drug Evaluation and Research. “These guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.”

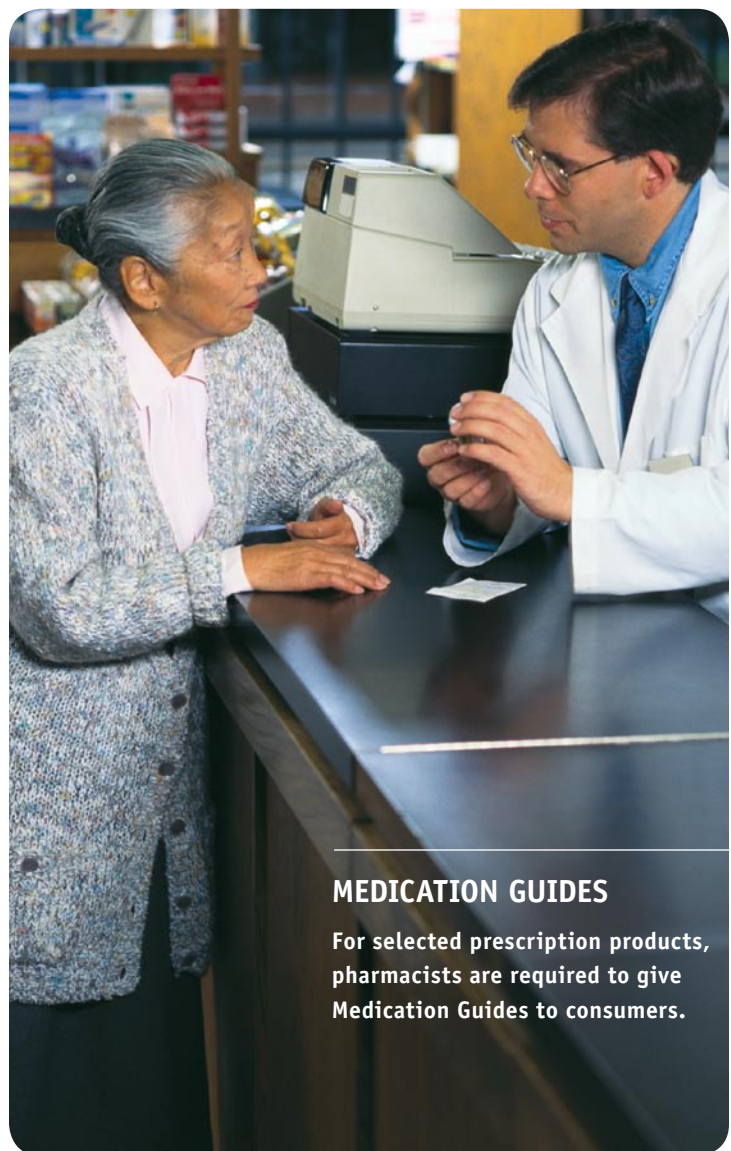
About 240 products that contain a medicine individually or in combination have Medication Guides available for them. To see a list of these, as well as online links to each Guide, visit [http://www.fda.gov/cder/Offices/ODS/medication\\_guides.htm](http://www.fda.gov/cder/Offices/ODS/medication_guides.htm)

### When are Medication Guides required?

Seligman explains that the guides are required to be issued with certain prescribed drugs and biological products when the Agency determines that

- certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or
- patient adherence to directions for the use of a product are essential to its effectiveness.

“Medication Guides generally focus on a specific risk or aspect of patient adherence, as opposed



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### MEDICATION GUIDES

For selected prescription products, pharmacists are required to give Medication Guides to consumers.

*‘The Medication Guide is part of the labeling. Regulations require that manufacturers produce them and alert pharmacists of their existence for certain medications. And pharmacists are required to distribute them to consumers.’*

to providing broader information on how to appropriately use a medicine,” says Seligman.

They offer answers to such crucial questions as

- What is this drug and what does it do?
- What’s the most important information that I need to know about the medication?
- What are the risks involved in taking this?
- What are the possible side effects?
- Who shouldn’t take the drug?
- What ingredients are in this medication?

**How are Medication Guides different from Consumer Medication Information Sheets?**

A Medication Guide is not the only handout that you may get with your prescription medicine. There is also a Consumer Medication Information Sheet, which is required for all new prescriptions.

The purpose of the Consumer Medication Information Sheet is to help all consumers understand key information about their prescription medicine, including how to take it, how to store it, and how to monitor improvement. It also gives information on precautions and warnings, as well as symptoms of serious or frequent

adverse events and what to do if you experience one.

“The Consumer Medication Information Sheet offers broader information on how to appropriately use a medicine, when compared to a Medication Guide,” says Seligman.

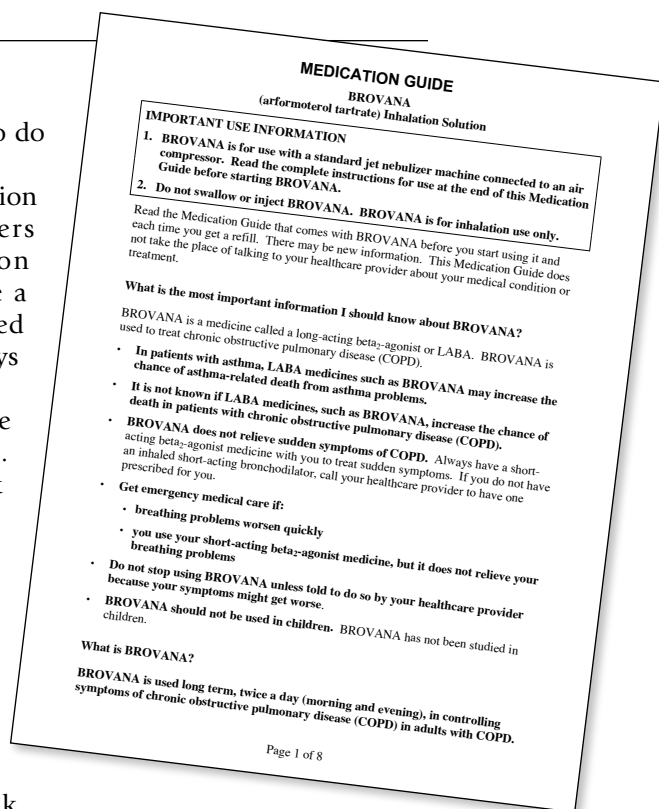
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**Give Feedback**

FDA is seeking feedback on its Medication Guide program. A public hearing will be held on the topic on June 12 and 13, 2007, from 8:30 a.m. to 4:30 p.m., at the National Transportation and Safety Board Boardroom and Conference Center in Washington, D.C.

Seligman says that goals of the hearing will include:

- assessing the effectiveness of Medication Guides in communicating the risks of certain drug and biological



**Sample of a Medication Guide**

- products to consumers
- identifying challenges and solutions linked to the distribution of Medication Guides.

For more information on the public hearing, visit [www.fda.gov/cder/meeting/medication\\_guides\\_200706.htm](http://www.fda.gov/cder/meeting/medication_guides_200706.htm)