

October 16, 2007

Conference call regarding FDA public meeting on Behind-the-Counter Drugs

Dear OCs OTC working group members,

Some of you may have heard that the FDA is planning a public meeting on behind-the-counter drugs that will take place on November 14. The FDA has invited the public to submit both written and oral comments for the meeting (the deadline to request to attend is November 5, and written comments will be accepted until November 28). In preparation for the meeting, RHTP has organized a call to discuss potential messages we might like to deliver at the meeting or in our comments, and anyone who is interested is welcome to call in.

Here are the details for the call:

Date: Monday, October 22
Time: 2:00 pm, Eastern Time

Below is a brief summary of the meeting, and attached is the full announcement. Please let me know if you have any questions...and I apologize for the short notice.

Thanks,
Dan

FDA Holding Public Meeting on Behind-the-Counter Drugs

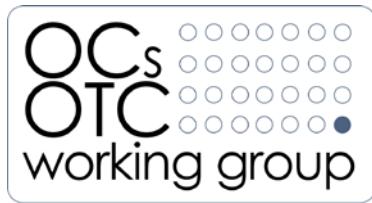
The FDA is holding a public meeting on whether it should make certain prescription drugs available behind the counter (BTC), which would not require customers to have a prescription but would require intervention by a pharmacist.

The purpose of the meeting, which will be held Nov. 14 in Washington, D.C., is to solicit opinions on such matters as the impact of the proposed BTC category on patient access to safe and effective drug products, as well as the effect on drug prices and patient compliance with drug therapy.

Some groups argue that pharmacists could talk to patients to ensure safe and effective use of a BTC drug that otherwise might require a prescription. These groups also argue that classifying certain drugs as BTC could increase patient access to medications that may be underutilized, particularly by patients without health insurance. BTC status is used in other countries, including Australia, Canada, France, New Zealand, the UK, Denmark, Germany, Italy, the Netherlands, Sweden and Switzerland.

Before switching a drug from prescription to BTC, most of these countries examine which of the drug's indications are suitable for self-medication, including self-diagnosis, with the help of a pharmacist, as well as the drug's potential for side effects or overdose and whether pharmacists can help minimize those risks.

Comments may be submitted to
www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA.



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