

FDA considers a third drug category: Behind-the-counter

By Rita Rubin, *USA TODAY*

Most everyone knows the USA has only two drug categories: prescription and over-the-counter, or non-prescription. Now the Food and Drug Administration is seeking public comment about a possible third category: behind-the-counter, or BTC.

Such drugs would be available without a prescription but only after asking a pharmacist for it, according to a Federal Register notice announced Wednesday. "FDA is exploring the public health benefit of certain drugs being available BTC (behind-the-counter) that were previously prescription medications," it says.

The FDA will seek public response at a meeting in Washington Nov. 14 and accept written comments until Nov. 28.

"The issue has become ripe," says Ilisa Bernstein, the FDA's director of pharmacy affairs. "We've heard from pharmacists that this is an issue. We've heard from manufacturers, from patients."

Bernstein emphasized: "We're not coming out and saying we think BTC is the way to go, and this is how it should be done. We want to find out more."

The FDA raises many questions about the concept in the Federal Register. They include:

- How might BTC drugs affect patient access?
- What's the role of a pharmacist or other health professional?
- If safety concerns arise, should BTC drugs go to prescription-only?

The American Society of Health System Pharmacists' policy since 1985 has been to advocate the creation of an "intermediary" category of drugs. The Consumer Healthcare Products Association, representing makers of non-prescription drugs and dietary supplements, opposes it.

With a BTC category, "patients would have some options, but it would hopefully be constructed to address any concerns about patient safety," says Brian Meyer, director of government affairs for the pharmacists' group.

David Spanger, senior vice president for policy and international affairs at the non-prescription-drugs organization, says: "You don't need a class. You've got flexibility in the existing system."

Manufacturers "can certainly be creative" on a product-by-product basis, Spanger says. He cites emergency contraceptive Plan B, which is available behind-the-counter without

a prescription to anyone 18 and older. The FDA opposed Duramed Pharmaceutical's plan to sell Plan B without a prescription to consumers of all ages.

When an FDA advisory panel met in January 2005 to discuss Merck's application to take cholesterol-lowering Mevacor over-the-counter, many panel members said they wished it could be sold behind-the-counter, the way Zocor, another Merck statin, is in the U.K. The committee voted 20-3 against OTC Mevacor, and the FDA followed its advice and turned Merck down.

In Canada, few drugs are BTC, says Gerry Harrington of NDMAC, the country's counterpart of Spanger's group. Many are "old, rarely used things," Harrington says. Among them: iodine, hydrocortisone in a 0.5% concentration and benzocaine to relieve teething pain.

The Federal Register notice can be found at www.fda.gov/OHRMS/DOCKETS/98fr/07n-0356-m00001.pdf.