Bextra: Valdecoxib or bucindolol?

Bextra (valdecoxib) was approved on Nov. 16, 2001, for the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis and for the treatment of primary dysmenorrhea. This COX-2 inhibitor is manufactured by G. D. Searle and is available as 10-mg and 20-mg tablets. Within three months of the product launch, the agency received two medication-error reports concerning potential confusion with the proprietary name.

The confusion stems from information that's available on the Internet concerning Bextra. Two practitioners (a pharmacist and a physician) searched the Internet for information on the newly approved valdecoxib product. However, they both discovered the proprietary name "Bextra" was linked to two different active ingredients, valdecoxib and bucindolol. This confused the pharmacist, physician, and possibly many other healthcare providers as well.

Proprietary names for unapproved products may be found on the Internet or through other types of electronic or written media. A manufacturer may choose to publish information on a proposed name prior to approval (e.g., Web sites, annual prospectus, etc.). This is what happened in the case of Bextra. Since the bucindolol product was not yet approved by the Food & Drug Administration and was undergoing phase III clinical trials, information pertaining to this proposed proprietary name would have been released solely at the manufacturer's discretion.

DMETS, FDA's Division of Medication Errors & Technical Support, conducted a "Bextra" Internet search to see what information is currently available on the worldwide Web. The search identified Bextra hits associated with both valdecoxib and bucindolol, the majority of which pertained to valdecoxib. The first reference to bucindolol was ranked number 145 of more than 3,000 hits. This reference referred to an article about the discontinued bucindolol phase III clinical trial.

A subsequent bucindolol reference pertained to information from manufacturer Intercardia's prospectus. Additionally, DMETS searched several commonly used electronic references—*eFacts*, *Physicians' Desk Reference*, *AHFS Drug Information* (2001), *Mosby's Drug Consult* (2002), and *USP Drug Information* (2002)—for any mention of bucindolol. None of the aforementioned references contained information on bucindolol.

Can this type of potential name confusion happen in the future? Unfortunately, it may. As previously noted, the decision to release information related to a proprietary name of an unapproved product falls under the manufacturer's purview only. Therefore, a manufacturer may decide on a name for a proposed product and release this information in various types of media before, or even after, submitting the proposed name to the FDA for review. The acceptability of a proprietary name by the FDA currently cannot be released to the public until the product has received final approval for marketing. So, how can a practitioner identify proprietary names and products that are approved by the FDA?

When searching the Internet for drug information, use the FDA Drug Approvals List (**www.fda.gov/cder/approval/index.htm**) to locate daily new drug and generic approval information. This site contains information on drugs approved from 1998 through 2002 and also includes information on the approval date and letter and package insert. Another resource is the FDA's Electronic Orange Book—Approved Drug Products with Therapeutic Equivalence Evaluations (**www.fda.gov/cder/ob/**). The Electronic Orange Book lists drug products approved by the FDA. Also available is an update of the Electronic Orange Book that contains monthly additions and deletions (**www.fda.gov/cder/rxotcdpl/pdplarchive.htm**). If the Internet is unavailable, call the FDA's toll-free number 1-(888) INFO-FDA (463-6332) for drug information.

Remember many sites on the Internet are not reliable sources for drug information. Healthcare practitioners should always verify drug information obtained from unfamiliar or unreliable Internet sources.

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To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.