

NONPRESCRIPTION MEDICINES DIGEST



December 2005

NMA extends warm holiday greetings and welcomes you to the winter edition of our quarterly NMA Newsletter. In this edition, we report an FDA call for comments on marketing of dual approved (Rx/OTC) ingredients and a final rule from the FDA on barring the use of the term "sinusitis" on product labeling of nonprescription decongestants. And lastly, as technology continues to evolve, the names we apply to overuse injuries evolves also, with the newest being "Blackberry thumb."

To catch up on the NMA 2005 Conference and view all of the abstracts from presented posters, agenda items, and news of next year's conference, go to <http://www.nmafaculty.org/conference.htm>.

[FDA Seeks Comments on Simultaneous Prescription and Nonprescription Marketing of Active Ingredients](#)

[FDA Issues a Final Rule Prohibiting Certain Sinus References on Nonprescription Product Labels](#)

[Newest Overuse Disorder: "Blackberry Thumb"](#)

FDA Seeks Comments on Simultaneous Prescription and Nonprescription Marketing of Active Ingredients

In a Federal Register publication on September 1, 2005 (pp. 52050-52051), the FDA reviewed the differences between prescription and nonprescription medications. The agency explained that it currently interprets the 1951 Durham-Humphrey Amendment to the 1938 FDC Act to allow marketing of the same active ingredient in Rx and OTC products, assuming that there is some meaningful difference between the two (e.g., indication, strength, route of administration, dosage form) that makes the Rx product safe only under the supervision of a prescriber.

This interpretation has allowed marketing of:

- Meclizine: Rx for vertigo; OTC for nausea with motion sickness
- Clotrimazole: Rx for candidiasis; OTC for tinea corporis, pedis, and cruris
- Loperamide: Rx for chronic diarrhea; OTC for acute diarrhea



Email this to
an associate.

Nicotine products, ibuprofen, and H2 blockers are also given dual status in similar situations. The agency has not yet allowed marketing of the same active ingredient in an Rx product for one population and in an OTC for a subpopulation. In this publication, the FDA sought comments on some interesting questions:

1. If the FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would the FDA be able to enforce this limitation as a matter of law? (Author's comment: Since the U.S. lacks a true third class of medications, nonprescription products may be sold in any location without any controls over who sells them or to whom they are sold. Thus, the answer to this would appear to be negative.)
2. Might these different products be sold legally in the same package? And if so, under what circumstances would this be acceptable?

It may be that a specific issue (e.g., a pending switch candidate) has driven the FDA to seek comments on this question. Most comment letters (accessed by following directions given in the Federal Register) reveal that readers assume the proposed rule will refer to Plan B.

FDA Issues a Final Rule Prohibiting Certain Sinus References on Nonprescription Product Labels

In a Federal Register published on October 11, 2005, the agency finalized a rule regarding nonprescription nasal decongestant products. The agency has become concerned about the large number of products containing nasal decongestants that offer to temporarily relieve nasal congestion associated with sinusitis for several reasons:

There is no evidence that decongestants are effective for sinusitis. Nevertheless, health care providers recommend them as adjunctive therapy. The agency stresses that this recommendation should only occur within a physician-patient relationship, and that consumers cannot self-diagnose nor can they self-manage sinusitis.

Topical nasal decongestants may even have a negative effect on the resolution of sinusitis by increasing the degree of sinus inflammation.

Self-treating sinusitis causes a lost opportunity to diagnose other serious medical conditions that mimic sinusitis or a possible delay in their diagnosis.

If the patient has bacterial sinusitis, the condition may worsen by delaying treatment with appropriate antibiotic medications, possibly resulting in serious complications.

For these reasons, the FDA is prohibiting use of any reference to sinusitis in the label of any nonprescription product. Products cannot claim to relieve nasal congestion associated with sinusitis, and cannot use the term "sinusitis" or "associated with sinusitis" in any context.

Products bearing prohibited labeling must remove it by April 1, 2007; however, products with annual sales of less than \$25,000 have until October 11, 2007. Failure to comply will allow the FDA to seize them as misbranded.

Newest Overuse Disorder: "Blackberry Thumb"

Pharmacists are often the primary consultation point for patients with repetitive motion disorders, also known as overuse disorders. They include aches and pains from long hours typing at a word processor, and common maladies such as writer's cramp. Whenever a new device appears that forces users to place a part of the body in an unnatural or stereotyped position for sustained periods, there is a risk of overuse disorder. "Nintendo thumb" is well known as a medical risk of long hours spent playing that device, resulting in a painful swelling at the base of the thumb. Computer use has caused "mouse wrist, mouse elbow, mouse shoulder, and mouse arm." The newest of these syndromes has been dubbed "Blackberry thumb," as reported by AP science writer Alicia Chang.

The Blackberry is a handheld wireless device that allows users to send emails in text message format from virtually any location. When people type on a standard computer keyboard, the fingers perform most of the work, and the thumb is relegated to punching the space bar. However, the Blackberry forces the thumb to become the dominant player, as both thumbs are used to type on the keypad. For heavy users, the thumb begins to throb as the tendons become inflamed. The pharmacist should counsel the patient with a less severe case to rest the thumb by ceasing use of the device for a period of time. Perhaps the patient will remain pain-free if their injury is less serious and if they use it with more restraint in the future. More seriously affected patients may require an enforced halt of thumb abuse through the use of thumb splinting, along with a pharmacist-suggested cryotherapy device. Cortisone injections may be helpful, and surgery may be required for the most severe cases.

If you would like to discontinue receiving the NMA newsletter, please [submit your request here](#).

Drake University
College of Pharmacy and Health Sciences
2507 University Avenue
Des Moines, Iowa 50311