



Consumer Healthcare
Products Association

June 28, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

Re: Docket No. 2003N-0539: Over-the-Counter Drug Products;
Safety and Efficacy Review

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) submits these comments on behalf of CHPA member companies who market over-the-counter (OTC) drugs for urinary pain relief. Our comments are in response to FDA's December 31, 2003 *Federal Register* notice (68 FR 75585-75591) requesting information about marketed urinary analgesic/antiseptic drug products that have not yet undergone evaluation in FDA's OTC drug review.

CHPA, founded in 1881, is the national association representing manufacturers and distributors of OTC drug products and dietary supplements. CHPA members account for over 90 percent of OTC drugs marketed in the United States, including several orally administered drug products for interim relief of urinary discomfort or pain. Accordingly, the association has important interest in this matter and welcomes the opportunity to comment on FDA's intention to review the active ingredients in those products for general recognition of their safety and effectiveness for their labeled uses. These comments are not meant to supersede comments submitted by individual members of CHPA.

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Action Requested:

FDA should review information on specific urinary analgesics submitted by individual manufacturers and establish an OTC monograph for the conditions under which those drugs would be generally recognized as safe and effective (GRASE) and not misbranded. The Agency would, in establishing the monograph, acknowledge the long and safe marketing record of these products.

Basis for Requested Action:

Under the OTC Drug Review, FDA systematically classifies OTC drugs by therapeutic category and determines conditions of use (active ingredients, indications, dosage forms, dosage strengths, dosage frequency, routes of administration, and labeling) under which products in each category would be generally recognized as safe and effective. Urinary analgesic products containing either a methenamine-sodium salicylate combination or phenazopyridine hydrochloride have been in widespread use without a prescription for decades. These drugs were identified as an OTC product category eligible for the OTC drug review, but they have not undergone that evaluation. As FDA stated in the December 31 *Federal Register* notice, resource limitations did not allow advisory panel review of every category of products being marketed when FDA established the OTC drug review in 1972, including urinary analgesic/antiseptic products.

FDA has nevertheless reviewed individual OTC urinary analgesic ingredients in the context of establishing a monograph for another drug category or as part of the Drug Efficacy Study Implementation (DESI) process. The OTC urinary analgesic sodium salicylate was reviewed as an active ingredient in the monograph for internal analgesics, and FDA has identified it as a Category I (GRASE) internal analgesic-antipyretic ingredient (53 FR 46204-46260, November 16, 1988). Products containing phenazopyridine were the subject of an FDA DESI notice (48 FR 34516, July 29, 1983) that specified conditions for their approval and marketing. Both ingredients have long histories of OTC use to show their safety and effectiveness for temporarily relieving pain and discomfort such as occurs with urinary tract infection while an affected person seeks and awaits professional medical attention.

According to Section 503 (b) (1) of the Food, Drug, and Cosmetic Act, a drug is suitable for nonprescription availability if it is safe for use by laypersons in self-medication on the basis of labeling without professional supervision. An important consideration for the appropriateness of self-medication is the ability of consumers to recognize the condition that can be effectively treated with an OTC drug. Such consumer recognition is clearly the case with urinary tract infection, which affects millions of persons and is likely to have a pattern of recurrence. Currently marketed OTC urinary analgesics are indicated for use to treat such readily recognized symptoms as burning or painful urination or sensations of urgency or frequent need for urination, which may accompany a urinary tract infection. The analgesic drug is not intended to cure infection, and consumers are directed in labeling statements to stop using the productS within a specific time and consult a doctor if pain persists or gets worse. The OTC urinary analgesic provides effective interim relief of symptoms until a physician can be consulted for a diagnosis and an antibiotic, if prescribed, takes effect.

Availability of FDA-approved OTC diagnostic test kits allows consumer to self-diagnose a urinary tract infection that requires a physician consultation to evaluate the need for treatment with a prescription antibiotic. Such diagnostic kits direct persons to see a physician if the test confirms a urinary tract infection or if symptoms persist beyond a short time limit even if the test results are negative.

Summary

The symptoms effectively relieved by an OTC urinary analgesic unquestionably are readily recognized by a sufferer and do not need confirmation by a healthcare professional before evaluation for antibiotic treatment. Urinary tract pain and discomfort can be successfully self-treated and relieved in the interim with currently available OTC urinary products. The products provide adequate label directions and warnings for safe and effective consumer self-medication.

Companies which market OTC urinary analgesic products will submit specific information to FDA about the active ingredients and their extensive history of safe use.

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FDA should review that information and establish an OTC monograph for the conditions under which urinary analgesics would be generally recognized as safe and effective (GRASE) and not misbranded.

Sincerely,



Lorna C. Totman, Ph.D., DABT
Senior Director of Scientific Affairs and Toxicology