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Consumer Healthcare
Products Association

October 31, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345
FDA Request for Comments on Advance Notice of Proposed Rulemaking, "Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product," 70 Fed. Reg. 52050-51 (September 1, 2005)

Dear Sir or Madam:

In the September 1, 2005, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced advance notice of proposed rulemaking (ANPR), regarding circumstances under which an active ingredient may be simultaneously marketed in both prescription and nonprescription, or over-the-counter (OTC), drug products.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of OTC medicines and dietary supplements in the United States. CHPA members account for over 90 percent of the domestic retail sales of OTC medicines. As such, we have an interest in the subject matter of the ANPR. CHPA sees no need for the agency to initiate a rulemaking on this matter. Sufficient precedent already exists for an active drug ingredient to be simultaneously marketed in both prescription and OTC drug products based on narrow distinctions.

The comments below use the numbering and lettering for questions on which FDA has invited comments (see 70 *Fed. Reg.* 52051 [September 1, 2005]).

1. A. FDA does not need to initiate a rulemaking to codify its interpretation regarding when an active ingredient can be simultaneously marketed in both a prescription and OTC drug product, since ample precedents already exist to guide the agency and the public. As the agency notes in the background information of this ANPR, the 1951 Durham-Humphrey Amendments to the Food, Drug and Cosmetic Act removed the confusion that had existed prior to that time when different manufacturers made different decisions about whether to market a drug as prescription or OTC. Under the Durham-Humphrey Amendments, the same drug, at the same dosage form and strength,

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and for the same indication, cannot simultaneously be available on a prescription and nonprescription basis.

But since the Durham-Humphrey Amendments, FDA has needed to draw fine distinctions among dosage forms, methods of administration, or indications or uses to regulate an ingredient differently in different settings. These fine distinctions are not limited to whether and when a drug ingredient is prescription or OTC. They run across a gamut of issues, from a product's primary mode of action to whether something is a food, drug, biologic, device, cosmetic, or some combination of them, from whether something is generally recognized as safe and effective or whether it requires a new drug application to other fine distinctions. The commonality in drawing these distinctions, and the very reason for drawing them, balances on whether or not an ingredient is the *same thing* in two related settings.

While FDA has established rules to help guide both interested parties and the agency in walking the line between various distinctions on what is or isn't the same and what triggers different treatment, there is no mandate to do so in every instance. In the case of the instant question of prescription and OTC status, there is no need for a rule, as there are ample precedents to give interested parties paths to follow to distinguish among different labeling requirements, leading to a drug active ingredient in two or more settings not being the "same," even if an outside observer less familiar with the nuances involved would not immediately see the distinctions. There are any number of instances where an active ingredient is seen as an OTC drug in one dosage form and strength for a specified indication(s), and also has uses or additional labeling under consultation with a health professional, whether those different uses or labeling are termed prescription use, professional labeling, professional information, or even off-label use.

The examples which follow provide a partial, not exhaustive, list of those instances where a particular ingredient is seen as an OTC drug in one or more settings, but is a prescription drug or includes prescription labeling, professional labeling, or professional information in others.

(1) Dosage strength variations. As FDA notes in the ANPR, ibuprofen and H2 blockers are both examples in which an ingredient is prescription in one strength and OTC in another. While FDA also pointed to more readily distinguished differing strengths and indications for the prescription or OTC ibuprofen and H2 blocker examples in the ANPR, one can also point to dosage strength variations where the distinctions between the prescription and OTC versions are finer. For example, prescription-strength 2.5 percent hydrocortisone cream is indicated for relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. OTC 1.0 or 0.5 percent hydrocortisone cream is indicated for temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to a number of listed inflammatory and pruritic conditions; i.e., indications closely related to the higher-dose prescription indication.