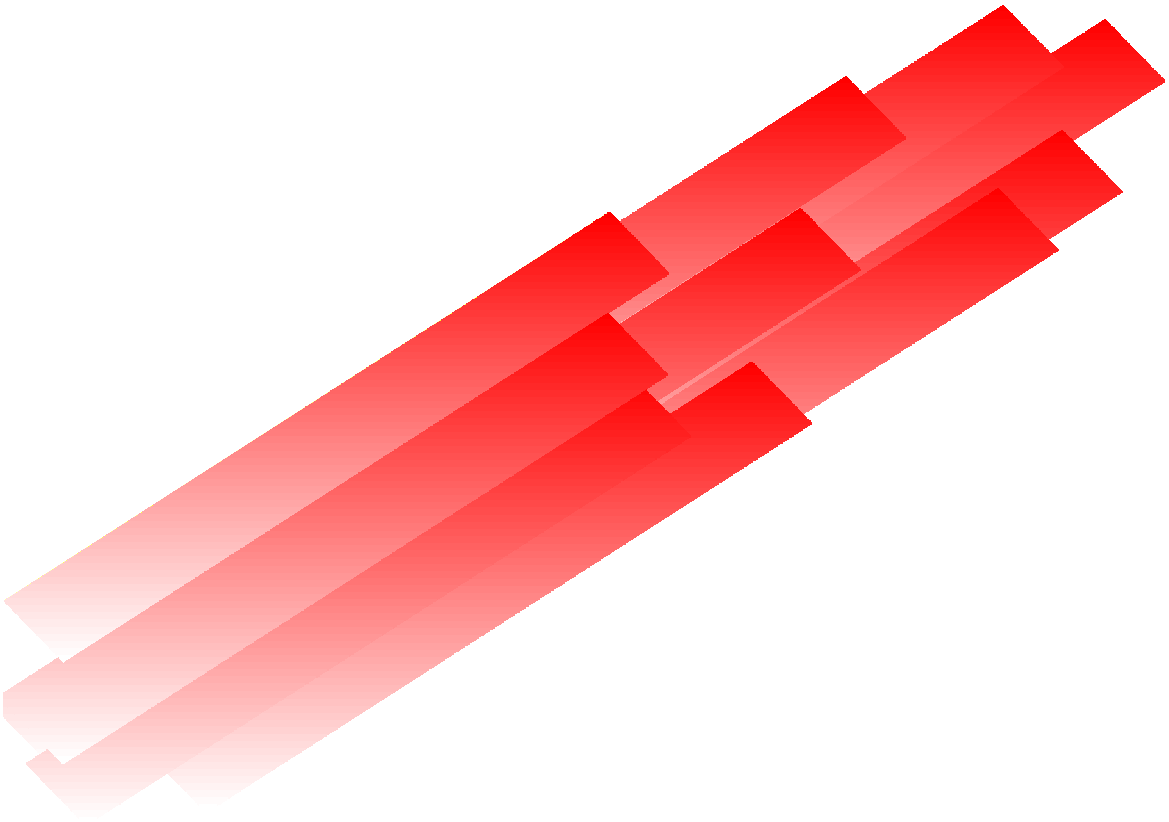
Guidance for Industry

National Uniformity for Nonprescription Drugs — Ingredient Listing for OTC Drugs



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
April 1998

Procedural Guidance #2

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I. INTRODUCTION

Section 412 of Title IV of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), signed into law by President Clinton on November 21, 1997, amended section 502(e) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 352(e)(1)) to require that the established name and quantity (or, if determined to be appropriate, the proportion) of each active ingredient appear on the label of all over-the-counter (OTC) drug products intended for human use.

In addition, section 502(e)(1), as amended by the Modernization Act, requires the listing of the established name of each inactive ingredient on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container as well, as prescribed in regulations promulgated by the Secretary. If the drug is an OTC drug that is not a cosmetic-drug, then the inactive ingredients must be listed in alphabetical order. These new requirements regarding the listing of inactive ingredients do not apply to nonprescription drugs that are not intended for human use.

This guidance is intended to clarify the administrative processes that will be followed in implementing these amendments to section 502(e) of the Act as they apply to OTC drug products for human use.

II. FDA POLICY — ACTIVE INGREDIENTS

In the *Federal Register* of February 27, 1997 (62 FR 9024), FDA proposed a rule that would establish a standardized format for the labeling of OTC drug products. The rule is intended to make OTC drug product labeling easier to read and understand and will require the redesign of OTC drug labels in accordance with a predetermined schedule of effective dates. The proposed rule includes a standardized format for listing the name and the quantity per dosage unit (or, when appropriate, the proportion) of each active ingredient.

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[1] This guidance has been prepared by the Regulations Policy Staff in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). This guidance represents the Agency's current thinking on implementation of the Modernization Act's amendments to section 502(e)(1) for OTC drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

To minimize the burden faced by manufacturers, packers, and distributors dealing with labeling changes, FDA advises that it does not intend to object if manufacturers, packers, and distributors choose to defer relabeling their products to comply with the new requirement to list the quantity of OTC active ingredients until no later than the earliest applicable implementation date as specified in the Agency's forthcoming final OTC labeling rule.

Full or abbreviated applications received after February 19, 1998, are expected to provide labels or labeling listing the quantity of active ingredients in compliance with the requirements of the Modernization Act.

III. FDA POLICY — INACTIVE INGREDIENTS

Section 502(e)(1)(iii) of the Federal Food, Drug, and Cosmetic Act, as amended by section 412(c) of the Modernization Act, states that a drug is misbranded unless its label bears "the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulations promulgated by the Secretary. . . ."

The Agency has received several letters since the signing of the Modernization Act from a trade association representing nonprescription drug manufacturers asking whether the phrase "as prescribed in regulations promulgated by the Secretary" modifies the entire provision, or only the clause regarding the listing of inactive ingredients on the immediate container.

Consistent with what it believes to have been the intent of this provision, the Agency intends to interpret both clauses — the clause for the listing of inactive ingredients on the outside container and the clause for the listing of inactive ingredients on the immediate container — as requiring implementing regulations before becoming effective.

The final rule establishing a standard format for the labeling of OTC drug products based on the proposed rule of February 27, 1997 (62 FR 9024), will provide the implementing regulations for this requirement of the Modernization Act for OTC drug products. The FDA will consider, as part of that rulemaking process, whether an additional opportunity for public comment is required for any provisions in the final rule that are intended to implement section 502(e)(iii) as amended by the Modernization Act.

This interpretation does not revoke or supersede in any way existing regulatory and statutory requirements governing the labeling of inactive ingredients.