Food and Drug Administration
Guide: OTC Drug Review Ingredient Report

This report contains an alphabetical listing of the ingredients considered in the OTC Drug Review that were classified and published in various *Federal Register* publications. This list includes over 2,700 ingredients (records) that provide a classification history throughout the rulemaking process. This guide describes the information presented in the report.

> Every effort has been made to ensure that this report is as complete and accurate as possible, but there may be deficiencies or errors. This report is NOT an official record recognized by the FDA and should only be used as an aid in researching the status of an OTC ingredient. Please report any discrepancies or errors so that clarifications may be made in order to provide an more accurate data base.

INGREDIENT

The ingredient names are listed in bold font at the top of the first column. The nomenclature used is in accordance with the "USAN" and "USP Dictionary of Drug Names." Ingredients with no official name are included using common names preferred by the agency. In some cases, Panels reviewed ingredients as a general class rather than as a single entity. Where this occurred, the general class is shown rather than the individual ingredient.

In some cases, the name of the ingredient has changed during the OTC drug review. The more recent (current) name is used for the ingredient categorization record in this report. The previous name has also been included with reference to the current name. For example, under the ingredient "phosphate, disodium," the reader is directed to see "sodium phosphate, dibasic."

PANEL

The bottom of the first column identifies the OTC Drug Advisory Panel responsible for evaluating each ingredient.

REPORT

OTC Drug Advisory Panels issued reports for various ingredients. Some panels issued more than one report. The name of reports referencing an ingredient is listed in the second column.

CATEGORY

The third column identifies the specific pharmacologic or therapeutic class (e.g., "sunscreen" or "expectorant") for each ingredient. In many cases, an ingredient is classified in more than one category. For example, the ingredient “acetaminophen” is classified in seven drug categories.

ANPR

An Advance Notice of Proposed Rulemaking (ANPR) is a published *Federal Register* document containing the conclusions and recommendations of an OTC Advisory Review Panel. This publication was designed to stimulate discussion, evaluation, and comment on the Panel's deliberations. Panel reports were prepared independently of FDA and represent the best scientific judgment of the panel members, but do not necessarily reflect the agency's position.

The OTC drug advisory panels utilized the following classification system for each ingredient reviewed:

- Category I: conditions under which OTC ingredients are generally recognized as safe and effective and are not misbranded
- Category II: conditions under which OTC ingredients are not generally recognized as safe and effective or are misbranded
- Category III: conditions under which the available data are insufficient to permit final classification at this time as Category I or II

For categories II and III, the reason for the categorization is symbolized by S (safety) and/or E (effectiveness).

PR

A proposed rule (PR) is a published *Federal Register* document containing a tentative final monograph (TFM) or regulation for ingredients in a specific drug category. A PR is based upon an evaluation of the Panel report and the comments and data received in response to publication of the ANPR. This document represents the agency's position and proposal on the ingredients.

FR

A final rule (FR) is a published *Federal Register* document containing a final monograph (FM) or regulation for ingredients in a specific drug category. An FR is based upon an evaluation of the comments and data received in response to publication of the PR. This document represents the agency's final position on the ingredients. At this stage, the categorization system (Category I, II, and III) is no longer used. Instead, references are made to applicable sections of "Title 21 [Food and Drugs] of the Code of Federal Regulations" (CFR) or the *Federal Register* publications.