U.S. FOOD & DRUG ADMINISTRATION

ANNUAL FORECAST FOR PLANNED MONOGRAPH ACTIVITIES

POSTING DATE: OCTOBER 1, 2021

The over-the-counter (OTC) monograph annual forecast is a nonbinding list, issued each year, of planned monograph activities that FDA intends to address over the ensuing 3 years. FDA's decision-making regarding which activities to place on the forecast is generally guided by public health priorities. The order of topics in the forecast does not reflect planned chronological order of FDA actions, or order of public health importance.

Topic	Activity Description	Current Data Request?[1]	Monograph Number	Related Prior Regulation(s)
Planned Proposed Safety Orders				
Risks Associated with Codeine-Containing Cough Medicine	Addresses the GRASE status of codeine, codeine phosphate, and codeine sulfate as antitussive active ingredients.	No[2]	M012	21 CFR 341
Pediatric Acetaminophen Dosing	Addresses dosage strengths of oral, single ingredient pediatric acetaminophen products. Proposes addition of weight- and age-based dosing for children under age 12 years.	No[2]	M013	21 CFR 201.326
Risks Associated with Propylhexedrine Abuse and Misuse	Proposes addition of a warning for propylhexedrine-containing drug products to inform consumers of serious health risks with abuse and misuse.	No[2]	M012	21 CFR 341.20(b)(9)
Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and Oligohydramnios	Proposes updated pregnancy labeling for NSAID-containing drug products	No[2]	M013	21 CFR 201.326 21 CFR 201.63

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Oral Healthcare in Infants and Children	Addresses the GRASE status of OTC oral health care drug products containing benzocaine and/or phenol preparations labeled for anesthetic/analgesic indications.	No[2]	M022	21 CFR 356
Serious Skin Reactions Associated with Acetaminophen	Proposes to add skin allergy warning to labeling requirements for acetaminophen-containing drug products.	No[2]	M013	21 CFR 201.326
Other Planned Proposed Orders				
Anticaries Test Methods	Addresses test methods for anticaries drug products.	No[2]	M021	21 CFR 355

1. FDA may request data in advance of a proposed order for certain types of planned actions, such as FDA-initiated finalization of general recognition of safety and effectiveness (GRASE finalization).
2. Data are not being requested at this time. Each proposed order will specify a comment period during which data and comments can be submitted.