

Index of Significant OTC Drug *Federal Register* Publications
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Division of Over-the-Counter Drug Products
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March 13	13590	OTC Drug Products Intended for Oral Ingestion that Contain Alcohol Final Rule (FR)
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April 19	19650	Drug Products Containing Quinine for the Treatment and/or Prevention of Malaria for OTC Human Use; Proposed Rule (PR)
April 24	20162	Exocrine Pancreatic Insufficiency Drug Products for OTC Human Use; Final Rule (FR)
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May 19	26853	Topical Drug Products Containing Benzoyl Peroxide; Required Labeling; Proposed Rule (PR); Extension of Comment Period
July 27	38636	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Combination Bronchodilator Drug Products Containing Theophylline; Final Rule (FR)
July 27	38643	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Proposed Amendment of Monograph for Bronchodilator Drug Products; Proposed Rule (PR)
Aug. 16	42435	Topical Drug Products for OTC Human Use; Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Partial Stay of Final Rule (FR)
Aug. 18	43091	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Proposed Amendment of Monograph for Bronchodilator Drug Products; Proposed Rule (PR); Correction
Aug. 21	43421	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Proposed Amendment of Monograph for Bronchodilator Drug Products; Proposed Rule (PR); Correction
Aug. 29	44787	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Proposed Amendment of Monograph for Bronchodilator Drug Products; Proposed Rule; Extension of Comment Period (PR)
Oct. 6	52474	Anticaries Drug Products for OTC Human Use; Final Monograph (FR)

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Feb. 14	5918	Topical Antimicrobial Drug Products for OTC Human Use; Proposed Amendment of Final Monograph for OTC First Aid Antibiotic Drug Products (NPR)
Feb. 14	5912	OTC Drug Products Containing Phenylpropanolamine; Required Labeling (PR)
March 4	8450	Labeling of Drug Products for OTC (PR)
March 5	8836	Antiflatulent Drug Products for OTC Human Use; Amendment of Monograph (FR)
March 8	9570	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; OTC Nasal Decongestant; Partial Stay of Final Rule; Enforcement Policy (FR)
April 9	15700	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Products Containing Diphenhydramine Citrate or Diphenhydramine Hydrochloride; Enforcement Policy (FR)
April 22	17798	Drug Labeling; Sodium Labeling for OTC Drugs (FR)
April 22	17807	Labeling of Orally Ingested OTC Drug Products Containing Calcium, Magnesium, and Potassium (NPR)
May 10	21392	OTC Drug Products Intended for Oral Ingestion That Contain Alcohol; Proposed Amendment of Final Rule (NPR)
May 20	25142	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Amendment of Monograph for OTC Bronchodilator Drug Products (FR)
June 13	30002	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for OTC Human Use; Proposed Amendment to the Tentative Final Monograph (NPR)
July 22	38046	Drug Labeling; Sodium Labeling for OTC Drugs; Extension of Comment Period (FR)

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July 22	38047	Labeling of Orally Ingested OTC Drug Products Containing Calcium, Magnesium, and Potassium; Extension of Comment Period (NPR)
Aug. 15	42398	Discussion of the Photochemistry and Photobiology of Sunscreens; Public Meeting and Reopening of the Administrative Record (Notification)
Aug. 19	42826	Labeling of Orally Ingested OTC Drug Products Containing Calcium, Magnesium, and Potassium; Correction (NPR; correction)
Sept. 16	48645	Sunscreen Drug Products for OTC Human Use; Amendment to the Tentative Final Monograph; (NPR)
Oct. 3	51625	Eligibility Criteria for Considering Additional Conditions in the OTC Drug Monograph System; Request for Information and Comments (ANPR)
Oct. 7	52285	Anticaries Drug Products for OTC Human Use; Final Monograph; Technical Amendment; Partial Delay of Effective Date (FR)
Oct. 11	53340	Sunscreen Drug Products for OTC Human Use; Amendment to the Tentative Final Monograph; Correction (NPR; correction)
Nov. 15	58471	Topical Antimicrobial Drug Products for OTC Human Use; Amendment of Final Monograph for OTC First Aid Antibiotic Drug Products
Nov. 18	58629	OTC Drug Products Intended for Oral Ingestion that Contain Alcohol; Amendment of Final Rule
Dec. 16	65944	Anticaries Drug Products for OTC Human Use; Partial Stay of Final Rule: Enforcement Policy (FR)
Dec. 19	66953	Vaginal Contraceptive Drug Products for OTC Human Use; Reopening of the Administrative Record

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Feb. 26	8663	Sunscreen Drug Products for OTC Human Use; Amendment to the TFM; (NPR Correction)
Feb. 27	9024	OTC Human Drugs; Proposed Labeling Requirements; (PR)
March 4	9684	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Amendment of Monograph for OTC Bronchodilator Drug Products; (FR Correction)
March 21	13733	Drug Labeling; Sodium Labeling for OTC Drugs; (FR Correction)
April 20	23350	Sunscreen Drug Products for OTC Human Use; Marketing Status of Products Containing Avobenzone; Enforcement Policy; (Announcement)
April 24	19923	Drug Labeling; Sodium Labeling for OTC Drugs; Partial Delay of Effective Date; (FR; partial delay of effective date)
June 19	33379	OTC Human Drugs; Proposed Labeling Requirements; Extension of Comment Period; (NPR; extension of comment period)
Aug. 29	45767	Labeling of Diphenhydramine-Containing Drug Products for OTC Human Use; (NPR) NOTE: This is a proposed amendment to the TFM for external analgesic, and the FM for antiemetic, antihistamine, antitussive, and nighttime sleep-aid indications.
Sept. 2	46223	Laxative Drug Products for OTC Human Use; Proposed Amendment to the TFM; (NPR)
Sept. 9	47532	Laxative Drug Products for OTC Human Use; Proposed Amendment to the TFM; (NPR Correction)
Oct. 9	52659	Antacid Drug Products for OTC Human Use; Amendment of Antacid Monograph; (CFR Correction)
Nov. 14	61041	OTC Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning; (NPR)

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Feb. 23	8888	Ophthalmic Drug Products for OTC Human Use; Proposed Amendment of Final Monograph; PR
March 20	13526	Drug Products Containing Quinine for the Treatment and/or Prevention of Malaria for OTC Human Use; (FR)
April 22	19799	Status of Certain Additional OTC Drug Category II and III Active Ingredients; Final Rule (FR)
May 21	27836	Package Size Limitation for Sodium Phosphates Oral Solution and Warning and Direction Statements for Oral and Rectal Sodium Phosphates for OTC Laxative Use; (FR)
May 21	27886	Laxative Drug Products for OTC Human Use; Proposed Amendment to the TFM; (NPR) (general and professional labeling for oral and rectal dibasic sodium phosphate/monobasic sodium phosphate (sodium phosphates) drug products))
June 19	33592	Laxative Drug Products for OTC Human Use; Proposed Amendment to the TFM; (NPR)
July 16	38412	Draft Guidance for Industry on Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis); Availability; (N)
July 20	38762	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Proposed Amendment of Final Monograph for OTC Antitussive Drug Products; (NPR)
July 30	40647	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products; (FR)
Aug. 13	43302	Pediculicide Drug Products for OTC Human Use; Final Monograph; Technical Amendment; (FR; technical amendment)
Aug. 17	46389	Pediculicide Drug Products for OTC Human Use; Final Monograph; Technical Amendment; (FR; technical amendment); Correction
Aug. 24	44996	Status of Certain Additional OTC Category II and III Active Ingredients; (FR)

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Oct. 23	56789	OTC Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning; (FR)
Oct. 23	56802	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for OTC Human Use; Final Rule for Professional Labeling of Aspirin, Buffered Aspirin, and Aspirin in Combination With Antacid Drug Products; (FR)
Dec. 7	67399	Drug Labeling; Warning and Direction Statements for Rectal Sodium Phosphates for OTC Laxative Use; Final Rule; Stay of Compliance; (FR; stay of compliance)
Dec. 9	67817	Laxative Drug Products for OTC Human Use; Partial Withdrawal of Proposed Amendment to the Tentative Final Monograph; Intent to Repropose; (NPR; withdrawal in part and intent to repropose)

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Jan. 29	4535	Laxative Drug Products for OTC Human Use; (FR)
March 17	13066	OTC Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning; Final Rule; Compliance Date
March 17	13254	OTC Human Drugs; Labeling Requirements; (FR)
April 15	18571	OTC Human Drugs; Labeling Requirements; Correction (FR; correction)
May 21	27666	Sunscreen Drug Products for OTC Human Use; (FM)
July 22	39452	Topical Antifungal Drug Products for OTC Human Use; Proposed Amendment of FM
Aug. 17	44653	OTC Drug Products Containing Colloidal Silver Ingredients or Silver Salts
Aug. 17	44671	Topical Otic Drug Products for OTC Human Use; Products for Drying Water-Clogged Ears; Proposed Amendment of Monograph
Sept. 14	49652	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for OTC Human Use; Final Rule for Professional Labeling of Aspirin, Buffered Aspirin, and Aspirin in combination with Antacid Drug Products; Technical Amendments; (FR; technical amendments)
Dec. 1	67291	Draft Guidance for Industry on Labeling of OTC Human Drug Products Using a Column Format; Availability (N)
Dec. 20	71062	Additional Criteria and Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded; (PR)

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Jan. 3	7	OTC Human Drugs; Labeling Requirements; Final Rule; Technical Amendment
June 8	36319	Sunscreen Drug Products for OTC Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record; Final Rule
June 20	38191	OTC Human Drugs; Labeling Requirements; Partial Extension of Compliance Dates; Final Rule
June 21	38426	Ophthalmic Drug Products for OTC Human Use; Amendment of Final Monograph; Final Rule
Aug. 1	46864	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Amendment of Final Monograph for OTC Antitussive Drug Products
Aug. 10	48902	Topical Otic Drug Products for OTC Human Use; Products for Drying Water-Clogged Ears; Amendment of Monograph; Lift of Partial Stay of Effective Date
Aug. 25	51780	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Reopening of the Administrative Record for Antihistamine Drug Products
Aug. 29	52302	Topical Antifungal Drug Products for OTC Human Use; Amendment of Final Monograph
Aug. 30	52775	Nonprescription Drugs Advisory Committee; Notice of Meeting (PPA)
Aug. 30	52775	Joint Meeting of the Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee; Notice of Meeting (Prilosec)
Dec. 19	79371	Draft Guidance for Industry on Labeling OTC Human Drug Products -- Submitting Requests for Exemptions and Deferrals; Availability
Dec. 19	79371	Guidance for Industry on Labeling OTC Human Drug Products Using a Column Format; Availability
Dec. 27	81739	Correction of 21 CFR 310.545 to add paragraph (d)(2)

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Feb. 22	11174	Draft Guidance for Industry on Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's; Availability
May 29	29059	Topical Antifungal Drug Products for OTC Human Use: Proposed Amendment of Final Monograph
June 22	33544	Request for Interest in Participating in the Selection of the Nonvoting Members of Industry Interests on Public Advisory Committees; Nonprescription Drugs Advisory Committee
Aug. 14	42665	Phenylpropanolamine; Proposal to Withdraw Approval of New Drug Applications and Abbreviated New Drug Applications; Opportunity for a Hearing
Sept. 27	49276	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Partial Final Rule for Combination Drug Products Containing a Bronchodilator
Sept. 27	49388	Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for OTC Drug Product Labeling
Oct. 15	52418	Anticaries Drug Products for Over-the-Counter Human Use; Use of Intraoral Appliance Models for compliance with Biological Testing Requirements; Request for Information and Comments
Oct. 19	53088	Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products for Over-the-Counter Human Use; Partial Final Rule for Combination Drug Products Containing a Bronchodilator. Correction
Dec. 31	67485	Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule

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Jan. 23	3060	Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded
Feb. 8	5942	Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph
Feb. 26	8818	Agency Information Collection Activities; Submission for OMB Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling
March 15	11571	Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph; Correction
March 15	11704	Anticaries Drug Products for Over-the-Counter Human Use; Use of Intraoral Appliance Models for Compliance with Biological Testing Requirements; Request for Information and Comments; Reopening of Comment Period
April 5	16304	Over-the-Counter Drugs; Labeling Requirements; Partial Delay of Compliance Dates
May 9	31123	Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients
May 9	31125	Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients
May 10	31739	Pediculicide Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph
May 15	34720	Agency Information Collection Activities; Announcement of OMB Approval; Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling
June 20	41821	Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment
Aug. 21	54139	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling

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Oct. 18	64402	Guidance for Industry on Labeling Over-the-Counter Human Drug Products - Updating Labeling in Reference Listed Drugs and Abbreviated New Drug Applications; Availability
Dec. 6	72555	Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use
Dec. 23	78158	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Final Monograph for Combination Drug Products

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Jan. 16	2254	Over-the-Counter Vaginal Contraceptive Drug Products Containing Nonoxynol 9; Required Labeling
Feb. 19	7919	Ophthalmic Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment
Feb. 19	7951	Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Proposed Amendment of Final Monograph for Over-the-Counter Ophthalmic Drug Products
April 14	17881	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for Combination Drug Products; Correction
April 17	18861	Labeling for Oral and Rectal Over-the-Counter Drug Products Containing Aspirin and Nonaspirin Salicylates; Reye's Syndrome Warning
April 17	18869	Antidiarrheal Drug Products for Over-the-Counter Human Use; Final Monograph
April 17	18915	Antidiarrheal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph
May 10	31739	Pediculicide Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph
May 29	32003	Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-Care Antiseptic Drug Products; Reopening of the Administrative Record
May 29	32232	Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph
June 3	32981	Ophthalmic Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment
June 3	33164	Guidance for Industry on Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate--Labeling Enforcement Policy; Availability

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June 4	33429	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling; Reopening of Comment Period
June 9	34273	Antiperspirant Drug Products for Over-the-Counter Human Use; Final Monograph
June 13	35290	Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Direct Final Monograph
June 13	35346	Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Proposed Rule