Index of Human OTC Drug Federal Register (FR) Publications
2000 through 2013
Volumes 65 through 78

Division of Nonprescription Regulation Development
Center for Drug Evaluation and Research
Food and Drug Administration

Federal Register in 2000 (Volume 65)

Date	FR Page	Document Title
Jan. 3	7	OTC Human Drugs; Labeling Requirements; Final Rule; Technical Amendment
June 6	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Dec. 19	79371	Draft Guidance for Industry on Labeling OTC Human Drug Products -- Submitting Requests for Exemptions and Deferrals; Availability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)

Federal Register in 2001 (Volume 66)

Date	FR Page	Document Title
Feb. 22	11174	Draft Guidance for Industry on Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's; Availability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

Federal Register in 2002 (Volume 67)

Date	FR Page	Document Title
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 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
Mar. 15	11571	Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment for Final Monograph; Correction
Mar. 15	11704	Anticaries Drug Products for Over-the-Counter Human Use; Use of Interaoral Appliance Models for Compliance with Biological Testing Requirements; Request for Information and Comments; Reopening of Comment Period
Apr. 15	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
Jun. 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
Oct. 4	62218	Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use; Proposed Rule
Oct. 18	64402	Guidance for Industry on Labeling Over-the-Counter Human Use; Proposed Rule

Federal Register in 2002 (Volume 67) (continued)

Date	FR Page	Document Title
Dec. 6	72555	Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use
Dec. 23	78158	Cold, Cough, Allergy, Bronchodilator, and Antisthmatic Drug Products for OTC Human Use; Final Monograph for Combination Drug Products

Federal Register in 2003 (Volume 68)

Date	FR Page	Document Title
Jan. 16	2254	Over-the-Counter Vaginal Contraceptive Drug Products Containing Nonoxynol 9; Required Labeling
Feb. 3	5299	Mercury Compounds in Drugs and Food, List
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
Apr. 14	17881	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use, Final Monograph for Combination Drug Products; Correction
Apr. 17	18861	Labeling for Oral and Rectal Over-the-Counter Drug Products Containing Aspirin and Nonaspirin Salicylates; Reye's Syndrome Warning
Apr. 17	18869	Antidiarrheal Drug Products for Over-the-Counter Human Use; Final Monograph
Apr. 17	18915	Antidiarrheal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph
May 7	24347	Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use
May 29	32003	Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-care Antiseptic Drug Products; Reopening of Administrative Record
May 29	32232	Oral HealthCare Drug Products for Over-the-Counter Human Use; Antiginigvitis/Antiplaque Drug Products; Establishment of Monograph
Jun. 3	32981	Ophthalmic Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment
Jun. 3	33164	Guidance for Industry on Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate – Labeling Enforcement Policy; Availability
Jun. 4	33362	Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph
Jun. 4	33429	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; propose Amendment of the Tentative Final Monograph

Federal Register in 2003 (Volume 68) (continued)

Date	FR Page	Document Title
Jun. 9	34273	Antiperspirant Drug Products for Over-the-Counter Human Use; Final Monograph
Jun. 13	35290	Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products, Final Monograph; Direct Final Rule
Jun. 13	35346	Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products, Final Monograph; Proposed Rule
Jun. 26	37963	Antidirheal Drug Products for Over-the-Counter Human Use; Final Monograph; Correction
Jul. 11	41386	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Sunscreen Ingredients
Jul. 17	42324	External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph
Aug. 1	45257	Mercury Compounds in Drugs and Food; List
Aug. 5	46133	Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph
Aug. 25	50991	Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph; Extension of Comment Period; Correction
Aug. 26	51167	Anorectal Drug Products for Over-the-Counter Human Use (Final Rule)
Oct. 6	57642	Oral Healthcare Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Products; Establishment of a Monograph; Extension of Comment Period; Correction
Oct. 9	58273	Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule; Confirmation of Effective date
Oct. 22	60302	Laxative Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record
Dec. 9	68509	Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph; Technical; Amendment
Dec. 31	75414	Pediculicide Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph
Dec. 31	75585	Over-the-Counter Drug Products; Safety Efficacy Review

Federal Register in 2004 (Volume 68)

Date	FR Page	Document Title
Jan. 22	3005	Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph, Direct Final Rule; and Confirmation of Effective Date; Corrections
Feb. 10	6309	Draft Guidance for Industry on Time and Extent Applications; Availability
Feb. 18	7652	Over-the-Counter Drug Products; Safety and efficacy Review, Additional Dandruff Control Ingredient
Mar. 24	13717	Drug Labeling; Sodium Labeling for Over-the-Counter Drugs; Technical amendment; Termination of Delay of effective Date; Compliance Dates
Mar. 24	13725	Drug labeling; orally Ingested Over-the-Counter Drug Products Containing Calcium. Magnesium. And Potassium
Mar. 24	13765	Drug Labeling; Sodium Labeling for Over-the-counter Drugs
May 12	26301	Antidiarheal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph
May 19	28932	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient; Extension of Comment Period
Ju.l 6	40640	Over-the-Counter Drug Products; Safety and Efficacy Review; Review Additional Antigingivitis/ Antiplaque Ingredient
Aug. 2	46119	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for Over-the-Counter Nasal Decongestant Drug Products
Aug. 19	51362	Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment
Aug. 23	51852	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Antidiarheal Ingredient
Sept. 3	53801	Over-the-Counter Human Drugs; Labeling Requirements; Delay of Implementation Date
Oct. 15	61148	Antiperspirant Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Reopening of the Administrative Record
Nov. 2	69278	Drug Labeling; Sodium Labeling for Over-the-Counter Drugs
Dec. 9	71420	Draft Compliance Guidance for Small Business Entities of Labeling Over-the-Counter Human Drug Products; Availability

Federal Register in 2005 (Volume 70)

Date	FR Page	Document Title
Jan. 4	362	Agency Information Collection Activities; Proposed Collection; Comment request; Format and Content Requirements for Over-the-Counter Drug Products Labeling
Jan. 5	741	Orally Administered Drug products for Relief of Symptoms Associated with Overindulgence in Food and Drink for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph
Jan. 13	2415	Draft Guidance for Industry on Labeling Over-the-Counter Human Drug products; Questions and answers; Availability
Mar. 29	15864	Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request. Format and Content for Over-the-Counter Drug Products Labeling
Mar. 29	15864	Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content for Over-the-Counter Drug Product Labeling
Jul. 11	39776	Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Over-the-Counter Human Drugs; Labeling Requirements
Jul. 13	40232	Cold, Cough. Allergy. Bronchodilator. And Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph for Combination Drug Products
Jul. 13	40237	Cold, Cough. Allergy. Bronchodilator. And Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph for Over-the-Counter Bronchodilator Drug Products
Oct. 11	58974	Cold, Cough. Allergy. Bronchodilator. And Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for Over-the-Counter Bronchodilator Drug Product
Dec. 5	72447	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Acne Ingredient
Dec. 5	72448	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient
Dec. 5	72449	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Sunscreen Ingredients

Federal Register in 2005 (Volume 70)(continued)

Date	FR Page	Document Title
Dec. 9	73178	Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products Containing Coal Tar and Menthol for Over-the-Counter Human Use; Proposed Amendment to the Monograph
Dec. 22	75988	Phenylpropanolamine – Containing Drug Products for Over-the-Counter Human Use; Tentative Final Monographs

Federal Register in 2006 (Volume 71)

Date	FR Page	Document Title
Jan. 13	2309	Phenylpropanolamine – Containing Drug Products for Over-the-Counter Human Use; Tentative Final Monographs; Correction
Jun. 22	35917	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Laxative Ingredient
Jul. 26	42405	Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Sunscreen Ingredients
Aug. 1	43358	Cold, Cough, Allergy Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Monograph for OTC Nasal Decongestant Drug Products
Aug. 29	51146	Skin Bleaching Drug Products for Over-the-Counter Human Use; Proposed Rule
Dec. 12	74474	Over-the-Counter Human Drugs; Labeling Requirements; Proposed Rule
Dec. 26	77314	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph

Federal Register in 2007 (Volume 72)

Date	FR Page	Document Title
Feb. 22	7941	Insect Repellent-Sunscreen Drug Products for Over-the-Counter Human Use; Request for Information and Comments
Mar. 6	9849	Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products Containing Coal Tar and Menthol for Over-th-Counter Human Use; amendment to the Monograph
Mar. 19	12730	Cold, Cough allergy. Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter, Technical Amendment
Mar. 29	14669	Laxative Drug Products for Over-the-Counter Human Use; Psyllium Ingredients in Granular Dosage Forms
Mar. 30	15043	New drugs Exempted From Prescription – Dispensing Requirements; Technical Amendment
Aug. 27	49070	Sunscreen Drug Products for Over-the Counter Human Use; Proposed Amendment of Final Monograph
Nov. 28	67264	Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Extension of Comment Period
Nov. 30	67639	Cold, Cough allergy. Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use, Final rule for Over-the-Counter Antitussive Drug Products; Technical Amendment
Dec. 19	71769	Over-the-Counter Vaginal Contraceptive and spermicide Drug Products Containing Nonoxynol 8; Require Labeling

Federal Register in 2008 (Volume 73)

Date	FR Page	Document Title
Jan. 3	402	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products
Feb. 1	6014	Skin Protectant Drug Products for Over-the-Counter Human Use; Reduced Labeling; Technical Amendment
Jun. 19	34895	Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients
Aug. 4	45227	Draft Guidance for industry on Labeling OTC Skin Protectant Drug Products; Availability
Aug. 25	50033	Over the Counter Cough and Cold Medications for Pediatric Use; Notice of Public Hearing
Sept. 2	51309	Over the Counter Cough and Cold Medication for Pediatric Use; Notice of Public Hearing; Correction
Sept. 12	53029	Ecamsule Eligibility for Inclusion in Monograph; Over-the-Counter Sunscreen Drug Products for Human Use; Request for Safety and Effectiveness Data
Oct. 28	63886	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products
Dec. 11	75436	Guidance for Industry on Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers; Availability
Dec. 12	75625	Withdrawal of Certain Proposed Rules and Other Proposed Actions

Federal Register in 2009 (Volume 74)

Date	FR Page	Document Title
Jan. 5	303	Guidance for Industry on Labeling Over-the-Counter Human Drug Products - Questions and Answers; Availability
Mar. 6	9759	Astringent Drug Products That Produce Aluminum Acetate; Skin Protectant Drug Products for Over-the-Counter Human Use; Technical Amendment
Apr. 7	15741	Sodium Shale Oil Sulfonate Eligibility for Inclusion in Monograph; Over-the-Counter Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Human Use; Request for Safety and Effectiveness Data
Apr. 29	19385	Final Monograph: Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use
May 1	20322	Draft Guidance for Industry on Label Comprehension Studies for Nonprescription Drug Products; Availability
Jun. 30	31177	Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph; Corrections
Jul. 14	34023	Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application
Aug. 20	42080	Educating the Public About Removal of Essential-Use Designation for Epinephrine; Public Workshop; Request for Comments
Sept. 1	45222	Guidance for Industry on Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers; Availability
Oct. 27	55245	Saccharomyces boulardii Eligibility for Consideration To Be Added to the Over-the-Counter Drug Monograph for Antidiarrheal Drug Products; Request for Safety and Effectiveness Data; Withdrawal
Nov. 5	57319	Draft Guidance for Industry on Dosage Delivery Devices for Over-the-Counter Liquid Drug Products; Availability
Nov. 25	61512	Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment

Federal Register in 2010 (Volume 75)

Date	FR Page	Document Title
Feb. 22	7606	Request for data: potential environmental impact
Mar. 4	9767	Classification of Benzoyl Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-The-Counter Human Use; Final Rule
May 4	23782	Drug Safety and Risk Management Advisory Committee; Notice of Meeting
June 2	30838	Drometrizole Trisiloxane Eligibility for Potential Inclusion in the Sunscreen Monograph; Over-the-Counter Sunscreen Drug Products for Human Use; Request for Safety, Effectiveness, and Environmental Data
June 3	31448	Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling
August 3	45641	Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling
August 13	49495	Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling
August 17	50770	Guidance for Industry on Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use--Small Entity Compliance Guide; Availability
October 8	62404	Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

Federal Register in 2011 (Volume 76)

Date	FR Page	Document Title
Jun 17	35620	Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Final Rule
Jun 17	35669	Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms; Final Rule
Jun 17	35672	Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Rule

Federal Register in 2011 (Volume 77)

Date	FR Page	Document Title
		NONE WAS PUBLISHED

Federal Register in 2013 (Volume 78)

Date	FR Page	Document Title
Dec 17	76444	Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record; Proposed Rule