

**INDEX OF SIGNIFICANT OTC DRUG
FEDERAL REGISTER PUBLICATIONS**

KEY

(N) Notice

1972-1981

(P) Proposal

(TF) Tentative Final Monograph

(F) Final

1982 +

(ANPR) Advance Notice of Proposed Rulemaking
(Previously (P))
(PR) Proposed Rule (monograph)
(Previously (TF))
(FR) Final Rule (monograph)
(Previously (F))

**Division of OTC Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20855
(301) 827-2222**

Rev: 6-26-96

**INDEX OF SIGNIFICANT OTC DRUG
FEDERAL REGISTER PUBLICATIONS**

Published in the FEDERAL REGISTER in 1972 (Volume 37)		
Date	FR Page	Document Title
1-5-72	85	OTC Drug Review Procedures (130) (P)
1-7-72	219	Hexachlorophene - SPI (3) (P)
5-11-72	9464	OTC Drug Review Procedures (130) (F)
5-20-72	10358	OTC Drug Review Procedures (130); Correction
9-27-72	20160	Hexachlorophene - SPI (3) (F)
11-4-72	23537	Hexachlorophene - SPI (3); Clarification
11-7-72	23644	Hexachlorophene - SPI (3); Correction

Published in the FEDERAL REGISTER in 1973 (Volume 38)		
Date	FR Page	Document Title
4-5-73	8714	Antacids (130) (P)
4-5-73	8714	General Conditions (130.302) (P)
5-29-73	14111	Antacids (130); Corrections
11-12-73	31258	General Conditions (130.302) (F)
11-12-73	31260	Antacids (130) (TF)
11-12-73	31269	General Conditions (130.301(iv)) (P)
12-7-73	33774	Antacids (130); Correction

Published in the FEDERAL REGISTER in 1974 (Volume 39)		
Date	FR Page	Document Title
1-8-74	1359	Antacid 1/21/74 Hearing (130) (N)
1-22-74	2488	Antacid - Modified Test Method (130.305) (P)
2-21-74	6620	Antacid (130); Correction
3-13-74	9659	General Conditions (130.301(iv)) (F)
6-4-74	19862	Antacid (331) (F)

6-4-74	19877	Antiflatulent (332) (F)
6-4-74	19878	OTC Procedures -- Administrative Record (130.10(a)(10)) (P)
6-4-74	19880	General Conditions (330.1) (P)
6-4-74	19882	Antacids -- NDA W/D (P)
6-20-74	22140	Antacid (130); Correction
9-11-74	32736	Antacid (130); Correction
9-13-74	33102	Tribromsalan Ban (310, 700) (P)
9-13-74	33103	Antimicrobial (333) (P)
11-8-74	39556	OTC Procedures -- Administrative Record (330.10(a)(10)) (F)
11-8-74	39591	Antacid - NDA W/D (F)

Published in the FEDERAL REGISTER in 1975 (Volume 40)

Date	FR Page	Document Title
3-13-75	11717	General Conditions (330.1) (F)
3-13-75	11718	Antacids (331) (P); Revised Labeling
3-21-75	12902	Laxative (334), Antidiarrheal (335), Antiemetic (336), and Emetic (337) (P)
5-23-75	22542	Antacids - Revised Effective Dates
5-23-75	22553	Antacids (331.20, 331.23) (P); Revised Test Procedure
6-5-75	24328	Aerosol Drug and Cosmetic Products Containing Zirconium Ban (310, 700) (P)
6-13-75	25218	Aerosol Drug and Cosmetic Products Containing Zirconium (700) (P); Correction
8-21-75	36574	Aerosol Drug and Cosmetic Products Containing Zirconium (310, 700) (P); Extension of Comment Period
10-15-75	48343	Antacids - Testing Procedures Amended (331.20, 331.23) (F)
10-21-75	49097	Testing Category III Active Ingredients (P)
10-30-75	50527	Tribromsalan Ban (310, 700) (F)
12-4-75	56675	Marketing Status of Ingredients Recommended for OTC Use (P)
12-8-75	57292	Nighttime Sleep-Aid (338), Daytime Sedative (339), and Stimulant (340) (P)
12-15-75	58165	OTC Drug Review Panel on Antacid Drug Products (availability of transcripts) (N)

Published in FEDERAL REGISTER in 1975 (Volume 41)

Date	Page	Document Title
1-8-76	1498	Nighttime Sleep-aid (338), Daytime Sedative (339) and Stimulant (340); Corrections
1-26-76	3745	Nighttime Sleep-aid (338), Daytime Sedative (339) and Stimulant (340); Correction
1-30-76	4600	Nighttime Sleep-aid (338), Daytime Sedative (339) and Stimulant (340); Correction
8-4-76	32580	Enforcement Policy for Marketing Ingredients for OTC Use (330.13) (F) OTC Human Drugs GRAS and GRAE and not misbranded.
9-9-76	38312	Cough, Cold, Allergy, Bronchodilator and Antiasthmatic (341) (P)
11-30-76	52536	Decision on Diphenhydramine as an Antitussive (N)
11-30-76	52537	Benylin Expectorant: NOH on Proposal to Deny Approval of Supplemental NDA for OTC Marketing as an Antitussive (N)
12-10-76	54032	Decision of Theophylline as a Single Ingredient--Disagreement with 9-9-76 CCABA Report

Published in FEDERAL REGISTER in 1977 (Volume 42)

Date	Page	Document Title
4-1-77	17642	Antibiotic (342) (P)
4-12-77	19137	Testing of Category III Ingredients (330) (F)
4-12-77	19156	Inactive Ingredients (201, 330) (P)
4-29-77	21816	Antibiotic (342); Correction
7-8-77	35346	Internal Analgesic, Antipyretic, and Antirheumatic (343) (P)
8-16-77	41374	Aerosol Drug and Cosmetic Products Containing Zirconium (310.510, 700.16) (F)
10-4-77	53980	Internal Analgesic, Antipyretic, and Antirheumatic (343); Extension of Time for Comments
10-11-77	54800	Amendment of Comment Period for Proposed Monographs for OTC Drugs (60 days to 90 days) (F)
10-28-77	56756	Phenylpropanolamine Dosage; Combination Products Containing Bronchodilator and an Antitussive (341); Clarification
12-16-77	63556	Otic (344) (P)

Published in FEDERAL REGISTER in 1978 (Volume 43)

Date	Page	Document Title
1-6-78	1100	Internal Analgesic, Antipyretic, and Antirheumatic (343); Extension of Time for Reply Comments
1-6-78	1210	Antimicrobial (333) (TF)
2-3-78	4637	Antimicrobial (333); Extension of Time for Reply Comments
5-2-78	18769	Dental Devices: Transfer of Administrative Responsibility from OTC Dental Panel to Bureau of Medical Devices (BMD) (F)
6-13-78	25544	Nighttime Sleep-aid (338) and Stimulant (340) (TF)
8-4-78	34628	Skin Protectant (347) (P)
8-25-78	38206	Sunscreen (352) (P)
9-5-78	39427	Antacid Wrap-Up Regulation (331) (F)
9-5-78	39544	Emetic (337) (TF)
9-19-78	42018	Skin Protectant (347); Correction
10-10-78	46694	Antiperspirant (350) (P)
11-3-78	51546	Skin Bleaching (358A) (P)
11-7-78	51806	Antiperspirant (350) (P); Correction
11-28-78	55417	Emetic (337); Correction
11-28-78	55464	Antacid Wrap-Up Regulation (331); Correction
11-28-78	55466	OTC Combination Drug Products (N); Availability of Guideline
12-1-78	56249	Sunscreen (352); Extension of Comment Period
12-12-78	58097	Sunscreen (352); Corrections
12-12-78	58097	Otic (344); Corrections
12-29-78	60957	Antiperspirant (350); Corrections
12-29-78	60957	Sunscreen (352); Corrections

Published in FEDERAL REGISTER in 1979 (Volume 44)

Date	Page	Document Title
3-6-79	12270	Transfer of Administrative Responsibility for Ophthalmic Hard Contact Lens Solutions Implementation (N)
3-6-79	12271	Transfer of Administrative Responsibility for Review of OTC Drug Products for the Treatment or Prophylaxis of Dandruff or Seborrhea Implementation (N)
3-9-79	13041	Antimicrobial (333); Reopening of the Administrative Record
3-16-79	16005	Vitamins and Mineral (Foods) Revocation of Regulations (F)
6-22-79	16126	Vitamins and Mineral (345) (P)
6-22-79	36378	Daytime Sedative (310.519) (F)
7-13-79	41064	Vitamin and Mineral (345); Extension of Comment and Reply Comment Periods
8-31-79	51512	Benylin; Final Decision (Warner-Lambert/Parke-Davis & Co.) (F)
9-21-79	54731	Antacid Amendment--Upset Stomach (331.30) (P)
10-2-79	56744	Benylin; Final Decision (Warner-Lambert/Parke-Davis & Co.); Correction
10-19-79	60316	Stomach Acidifier (310.540) (P)
10-19-79	60328	Antacid Amendment (Calcium, Magnesium Tetracycline Warning) (331.30) (P)
10-26-79	61608	Category III Policy Intent to Revise Rule (330) (P)
10-26-79	61609	Antimicrobial (333); Reopening of the Administrative Record
10-26-79	61610	Antiemetic (336); Reopening of the Administrative Record
10-26-79	61611	Nighttime Sleep-aid and Stimulant (338, 340); Reopening of the Administrative Record
11-2-79	63270	Oral Mucosal Injury (353) (P)
11-16-79	65992	Antacid Amendment (Calcium Magnesium Tetracycline Warning) (331.30); Correction
11-16-79	65992	Nighttime Sleep-aid and Stimulant; Reopening of the Administrative Record (338, 340); Correction
12-4-79	69768	External Analgesic (349) (P)
12-11-79	71428	Antimicrobial (333); Reopening of Administrative Record
12-21-79	75666	Exocrine Pancreatic Insufficiency (357) (P)