DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

ıblic Health Service (PHS)—Food and Drug Administration (FDA)

1247. OVER-THE-COUNTER (OTC) DRUG REVIEW

Significance:
Subject to OMB review: Undetermined

Legal Authority: 21 USC 321p; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360a; 21 USC 371a

CFR Citation: 21 CFR 310; 21 CFR 330; 21 CFR 333; 21 CFR 334; 21 CFR 335; 21 CFR 336; 21 CFR 337; 21 CFR 338; 21 CFR 339; 21 CFR 340; 21 CFR 341; 21 CFR 342; 21 CFR 343; 21 CFR 344; 21 CFR 345; ...

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. NOTE: NPRM for "Antidotes, Toxic Ingestion Products" was combined with NPRM for "Emetic Products" and reproposed as "Poison Treatment Products." NPRM for "Astringent (Wet Dressings) Products" was included in the NPRM for "Skin Protectant Products." NPRM for "Diaper Rash Products" was included in NPRMs for "Antifungal," "Antimicrobial," "External Analgesic" and "Skin Protectant Products." NPRM for "Fever Blister/Cold Sore Products (External)" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Insect Bites and Stings (Relief) Products" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." "Poison Ivy/Oak/Sumac Prevention" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Mercurial (Topical) Products" to be included in revised NPRM (cont)

Timetable:

Acne (Topical) Products
- ANPRM 03/23/82 (47 FR 12430)
- NPRM 01/15/85 (50 FR 2172)
- NPRM (Amendment) 08/07/91 (56 FR 37622)
- Final Action 08/16/91 (56 FR 41008)

Alcohol (Oral) in OTC Drug Products
- NPRM 10/21/93 (58 FR 54466)

ıcohol (Topical) Products (To be merged w/other rulemkg)
- ANPRM 05/21/82 (47 FR 22324)

Anorectal Products
- ANPRM 05/27/80 (45 FR 35576)
- NPRM 08/15/88 (53 FR 30756)
- Final Action 08/03/90 (55 FR 31776)
- Final Action (LYCD) 09/02/93 (58 FR 46746)
- Final Action (Witch Hazel) 07/00/94

Antacid Drug Products
- ANPRM 04/05/73 (38 FR 8714)
- NPRM 11/12/73 (38 FR 31260)
- Final Action 06/04/74 (39 FR 9862)
- NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66754)
- Final Action (Amendment) (Warning) 08/26/93 (58 FR 45204)
- NPRM (Amendment) (Testing) 09/23/93 (58 FR 49826)
- NPRM (Amendment)(Sodium Bicarb.) 02/02/94 (59 FR 5060)

Anthelmintic Products
- ANPRM 09/09/80 (45 FR 59541)
- NPRM 08/24/82 (47 FR 37062)
- Final Action 08/01/86 (51 FR 27756)

Antibiotic First Aid Products
- ANPRM 04/01/77 (42 FR 17642)
- NPRM 07/09/82 (47 FR 29986)
- Final Action 12/11/87 (52 FR 47312)
- NPRM (Amendment) 08/18/89 (54 FR 34188)
- Final Action 03/15/90 (55 FR 9721)
- NPRM (Amendment) 05/11/90 (55 FR 19868)
- NPRM (Amendment) 06/08/90 (55 FR 23450)
- Final Action (Amendment) 10/03/90 (55 FR 40379)
- Final Action (Amendment) 12/05/90 (55 FR 50171)

Anticaries Products
- ANPRM 03/28/80 (45 FR 20666)
- NPRM 09/30/85 (50 FR 39854)
- NPRM 06/15/88 (53 FR 22430)
- Final Action 09/00/94

Antidiarrheal Products
- ANPRM 03/21/75 (40 FR 12924)
- NPRM 04/30/86 (51 FR 16138)
- Final Action 09/00/94

Antidotes, Toxic Ingestion Prdts (Now Poison Treatment Prdts)
- ANPRM 01/05/82 (47 FR 444)

Antiemetic Products
- ANPRM 03/21/75 (40 FR 12934)
- NPRM 07/13/79 (44 FR 41064)
- Final Action 04/30/87 (52 FR 15886)
- NPRM (Amendment) 08/26/93 (58 FR 45216)
- Final Action 04/00/94

Antiflatulent Drug Products
- NPRM 11/12/73 (38 FR 31260)
- Final Action 06/04/74 (39 FR 19877)
- NPRM (Amendment) 01/29/88 (53 FR 2716)

Antifungal (Topical) Products
- ANPRM 03/23/82 (47 FR 12480)
- NPRM 12/12/89 (54 FR 51136)
- NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25240)
- Final Action (Amdt.)(Diaper Rash) 12/18/92 (57 FR 60430)
- Final Action (Partial) 09/02/93 (58 FR 46744)
- Final Action 09/23/93 (58 FR 49890)

Antimicrobial Products
- ANPRM 09/13/74 (39 FR 33103)
- NPRM 01/06/78 (43 FR 1210)
- NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25246)

Antiperspirant Products
- ANPRM 10/10/78 (43 FR 46694)
- NPRM 08/20/82 (47 FR 36492)
- Final Action 00/00/00

Antiseptic First Aid
- ANPRM 09/13/74 (39 FR 33103)
- NPRM 01/06/78 (43 FR 1210)
- NPRM (Revised) 07/22/91 (56 FR 33644)
- Final Action 00/00/00

Antiseptic Products (Professional Use)
- ANPRM 09/13/74 (39 FR 33103)
- NPRM 01/06/78 (43 FR 1210)
- NPRM (Revised) 09/00/94

Aphrodisiac Products
- ANPRM 10/01/82 (47 FR 43572)
- NPRM 01/15/85 (50 FR 2168)
- Final Action 07/07/89 (54 FR 28780)

Aspirin (Heart Labeling)
- NPRM 10/20/93 (58 FR 54224)

Aspirin (Reye Syndrome)
- NPRM 10/20/93 (58 FR 54228)

Astringent (Wet Dressings) Prdts (Merged w/other rulemkg)
- ANPRM 09/07/82 (47 FR 39436)

Benign Prostatic Hypertrophy Products
- ANPRM 10/01/82 (47 FR 43566)
- NPRM 02/20/87 (52 FR 5406)
- Final Action 02/27/90 (55 FR 6926)

Boil Ointments
- ANPRM 06/29/82 (47 FR 28306)
- NPRM 01/26/88 (53 FR 2198)
- Published 11/15/93 (58 FR 60332)

Camphorated Oil Drug Products
- ANPRM 09/26/80 (45 FR 63869)
- Final Action 09/21/82 (47 FR 41716)

Cholecystokinetic Products
- ANPRM 02/12/80 (45 FR 9286)
- NPRM 08/24/82 (47 FR 37068)
- Final Action 06/10/83 (48 FR 27004)
- NPRM (Amendment) 08/15/88 (53 FR 30786)
- Final Action (Amendment) 02/28/89 (54 FR 8320)

Corn and Callus Remover Products
- ANPRM 01/05/82 (47 FR 522)
- NPRM 02/20/87 (52 FR 5412)
- Final Action 08/14/90 (55 FR 33258)

Cough/Cold (Anticholinergic) Products
- ANPRM 09/09/76 (41 FR 38312)
- NPRM 07/09/82 (47 FR 30002)
- Final Action 11/08/85 (50 FR 46582)

Cough/Cold (Antihistamine) Products
- ANPRM 09/09/76 (41 FR 38312)
- NPRM 01/15/85 (50 FR 2200)
- NPRM (Amendment) 08/24/87 (52 FR 31892)
- Final Action 12/09/92 (57 FR 58356)
- Final Action (Amendment)(Warning) 01/28/94 (59 FR 4216)

Cough/Cold (Antitussive) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/19/83 (48 FR 48576)
Final Action 08/12/87 (52 FR 30042)
NPRM (Amendment) 07/06/89 (54 FR 28442)
NPRM (Amendment) 10/02/89 (54 FR 40412)
Final Action (Amendment) 07/06/90 (55 FR 27806)
Final Action (Amendment) 10/03/90 (55 FR 40381)
NPRM (Amendment)(Warning) 06/19/92 (57 FR 27666)
NPRM (Amendment)(Ingredients) 12/09/92 (57 FR 58378)
Final Action (Amendment)(Warning) 10/20/93 (58 FR 54232)
Final Action (Amdt.)(Ingredients) 08/00/94

Cough/Cold (Bronchodilator) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/26/82 (47 FR 47520)
Final Action 10/02/86 (51 FR 35326)
NPRM (Amendment)(Warning) 06/19/92 (57 FR 27662)
Final Action (Amendment)(Warning) 10/20/93 (58 FR 54238)

Cough/Cold (Combination) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 08/12/88 (53 FR 30522)
Final Action 00/00/00

Cough/Cold (Expectorant) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 07/09/82 (47 FR 30002)
Final Action 02/28/89 (54 FR 8494)
Final Action (Technical Changes) 06/30/92 (57 FR 29176)

Cough/Cold (Expectorant/Ipecac) Products
Final Action 09/14/92 (57 FR 41857)

Cough/Cold (Nasal Decongestant) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 01/15/85 (50 FR 2220)
NPRM (Amendment) 06/19/92 (57 FR 27658)
Final Action 09/00/94

Dandruff, Seborrheic Dermatitis and Psoriasis Control Products
ANPRM 12/03/82 (47 FR 54646)
NPRM 07/30/86 (51 FR 27346)
Final Action 12/04/91 (56 FR 63554)
NPRM (Amendment) 04/05/93 (58 FR 17554)
Final Action 01/28/94 (59 FR 4000)

Daytime Sedatives
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 06/22/79 (44 FR 36378)

Diaper Rash Products (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39406)

Digestive Aid Products
ANPRM 01/05/82 (47 FR 454)
NPRM 01/29/88 (53 FR 2706)
Final Action 10/21/93 (58 FR 54450)

Emetic Products
ANPRM 03/21/75 (40 FR 12939)
NPRM 09/05/78 (43 FR 39544)

Exocrine Pancreatic Insufficiency Products
ANPRM 12/21/79 (44 FR 75666)
NPRM 11/08/85 (50 FR 46594)
NPRM (Reproposed) 07/15/91 (56 FR 32282)
Final Action 00/00/00

External Analgesic Products
ANPRM 12/04/79 (44 FR 69768)
NPRM 02/08/83 (48 FR 5852)
NPRM (Amendment) (Dandruff) 07/30/86 (51 FR 27360)
NPRM (Amendment) (Anorectal) 08/25/88 (53 FR 32592)
NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40818)
NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3370)
NPRM (Amendment) (1%Hydrocortisone) 02/27/90 (55 FR 6932)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25234)
Final Action (Diaper Rash) 12/18/92 (57 FR 60426)
Final Action 00/00/00

Fever Blister Products (Internal)
ANPRM 01/05/82 (47 FR 502)
NPRM 06/17/85 (50 FR 25156)
Final Action 06/30/92 (57 FR 29166)

Fvr Blister/Cold Sore Prdts (Ext.) (To be merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39436)

Hair Grower and Hair Loss Prevention Products
ANPRM 11/07/80 (45 FR 73955)
NPRM 01/15/85 (50 FR 2190)
Final Action 07/07/89 (54 FR 28772)

Hormone (Topical) Products
ANPRM 01/05/82 (47 FR 430)
NPRM 10/02/89 (54 FR 40618)
Final Action 09/09/93 (58 FR 57608)

Hypo/Hyperphosphatemia Products
ANPRM 12/09/80 (45 FR 81154)
NPRM 01/15/85 (50 FR 2160)
Final Action 05/11/90 (55 FR 19852)

Ingrown Toenail Relief Products
ANPRM 10/17/80 (45 FR 69128)
NPRM 09/03/82 (47 FR 39120)
Final Action 09/09/93 (58 FR 47602)

Insect Bite & Sting (Relief) Prdts (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39412)

Insect Repellent Drug Products (Internal)
ANPRM 01/05/82 (47 FR 424)
NPRM 06/10/83 (48 FR 26986)
Final Action 06/17/85 (50 FR 25170)

Internal Analgesic Products
ANPRM 07/08/77 (42 FR 35346)
NPRM 11/16/88 (53 FR 46204)
NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66762)
NPRM (Amdt.)(Sodium Bicarbonate) 02/02/94 (59 FR 5068)

Internal Analgesic Products (Overindulgence)
Final Action 00/00/00

Internal Deodorant Products
ANPRM 01/05/82 (47 FR 512)
NPRM 06/17/85 (50 FR 25162)
Final Action 05/11/90 (55 FR 19862)

Labeling of Drug Products for OTC Use
NPRM 04/05/93 (58 FR 17553)
Final Action 01/28/94 (59 FR 3998)

Laxative Products
ANPRM 03/21/75 (40 FR 12902)
NPRM 01/15/85 (50 FR 2124)
NPRM (Amendment) 10/01/86 (51 FR 35136)
NPRM (Amendment) 09/02/93 (58 FR 46589)
Final Action 00/00/00

Leg Muscle Cramps (Nocturnal Relief) Products
ANPRM 10/01/82 (47 FR 43562)
NPRM 11/08/85 (50 FR 46588)
Final Action 09/00/94

Male Genital Desensitizer Products
ANPRM 09/07/82 (47 FR 39412)
NPRM 10/02/85 (50 FR 40260)
Final Action 06/19/92 (57 FR 27654)

Menstrual Products
ANPRM 12/07/82 (47 FR 55075)
NPRM 11/16/88 (53 FR 46194)

Mercurial (Topical) Products (To be merged w/other rulemkg)
ANPRM 01/05/82 (47 FR 436)

Nailbiting/Thumbsucking Deterrent Products
ANPRM 10/17/80 (45 FR 69122)
NPRM 09/03/82 (47 FR 39096)
Final Action 09/02/93 (58 FR 46749)

Nighttime Sleep Aid Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/14/89 (54 FR 6814)
NPRM (Amendment) 08/26/93 (58 FR 45217)
Final Action (Amendment) 04/00/94

NDA Labeling Exclusivity
NPRM 11/09/93 (58 FR 59622)

Ophthalmic Products
ANPRM 05/06/80 (45 FR 30002)
NPRM 06/28/83 (48 FR 29788)
Final Action 03/04/88 (53 FR 7076)
Final Action (Anti-infective) 12/18/92 (57 FR 60416)

Oral Discomfort (Relief) Products
ANPRM 05/25/82 (47 FR 22712)
NPRM 09/24/91 (56 FR 48302)

Oral Health Care Products
ANPRM 05/25/82 (47 FR 22760)
NPRM 01/27/88 (53 FR 2436)
NPRM (Amendment) (Antimicrobials) 02/09/94 (59 FR 6084)
Final Action 00/00/00

Oral Mucosal Injury Products (Merged w/Oral Health Care)
ANPRM 11/02/79 (44 FR 63270)
NPRM 07/26/83 (48 FR 33984)

Oral Wound Healing Products
ANPRM 11/02/79 (44 FR 63270)
NPRM 07/26/83 (48 FR 33984)
Final Action 07/18/86 (51 FR 26112)

Otic Products (Earwax)
NPRM 07/09/82 (47 FR 30012)
Final Action 08/08/86 (51 FR 28656)

Otic Products (Swimmers Ear)
NPRM 07/30/86 (51 FR 27366)
Final Action 09/00/94

Overindulgence Remedies
ANPRM 10/01/82 (47 FR 43540)
NPRM 12/24/91 (56 FR 66742)
NPRM (Amendment)(Warning) 05/05/93 (58 FR 26886)

Overindulgence Remedies/Prevention of Inebriation
ANPRM 10/01/82 (47 FR 43540)
Final Action 07/19/83 (48 FR 32872)
Pediculicide Products
ANPRM 06/29/82 (47 FR 28312)
NPRM 04/03/89 (54 FR 13480)
Final Action 12/14/93 (58 FR 65452)
Poison Ivy/Oak/Sumac Prevention (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39412)
Poison Treatment Products
NPRM 01/15/85 (50 FR 2244)
Final Action 09/00/94
Reporting of Adverse Reactions
NPRM 06/00/94
Skin Bleaching Products
ANPRM 11/03/78 (43 FR 51546)
NPRM 09/03/82 (47 FR 39108)
NPRM (Reproposed) 09/00/94
Skin Protectant Products
ANPRM 08/04/78 (43 FR 34628)
NPRM 02/15/83 (48 FR 6820)
NPRM (Amendment) (Astringent) 04/03/89 (54 FR 13490)
NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40808)
NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3362)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25204)
Final Action (Astringent) 10/21/93 (58 FR 54466)
Final Action (Witch Hazel) 07/00/94
Final Action 00/00/00
Smoking Deterrent Products
ANPRM 01/05/82 (47 FR 490)
NPRM 07/03/85 (50 FR 27552)
Final Action 06/01/93 (58 FR 31236)
Sodium Labeling
NPRM 04/25/91 (56 FR 19222)
Final Action 00/00/00
Status of Certain Category II and III Ingredients
NPRM 05/16/90 (55 FR 20434)
Final Action 11/07/90 (55 FR 46914)
NPRM 08/25/92 (57 FR 38568)
Final Action 05/10/93 (58 FR 27636)
Stimulant (Overindulgence) Products
NPRM (Amendment) 12/24/91 (56 FR 66758)
Stimulant Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/29/88 (53 FR 6100)
Stomach Acidifier Products
ANPRM 10/19/79 (44 FR 60316)
NPRM 01/15/85 (50 FR 2184)
Final Action 08/17/88 (53 FR 31270)
Sunscreen Products
ANPRM 08/25/78 (43 FR 38206)
NPRM 05/12/93 (58 FR 28194)
Sweet Spirits of Nitre
ANPRM 02/22/80 (45 FR 11846)
Final Action 06/27/80 (45 FR 43400)
Topical Drug Products Containing Benzoyl Peroxide (Labeling)
NPRM 07/00/94
Vaginal Contraceptive Products
ANPRM 12/12/80 (45 FR 82014)
NPRM 07/00/94
Vaginal Drug Products
ANPRM 10/13/83 (48 FR 46694)
Withdrawal Published 02/03/94 (59 FR 5226)
Vitamin/Mineral Products
ANPRM 03/16/79 (44 FR 16126)
Withdrawal 11/27/81 (46 FR 57914)
Wart Remover Products
ANPRM 10/03/80 (45 FR 65609)
NPRM 09/03/82 (47 FR 39102)
NPRM (Amendment) 03/27/87 (52 FR 9992)
Final Action 08/14/90 (55 FR 33246)
NPRM (Amendment)(Directions) 01/28/94 (59 FR 4015)
Water Soluble Gums
NPRM 10/30/90 (55 FR 45782)
Final Action 08/26/93 (58 FR 45194)
Weight Control Products
ANPRM 02/26/82 (47 FR 8466)
NPRM 10/30/90 (55 FR 45788)
Final Action 08/08/91 (56 FR 37792)
NPRM (Amendment) 09/00/94

Small Entities Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: for "Antimicrobial Products." NPRM for "Alcohol (Topical) Products" to be included in revised NPRM for "Antimicrobial Products." The NPRM for "Antimicrobial Products" is being revised because it is being updated and split into two sections: first aid products and health care products.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Agency Contact: William E. Gilbertson, Director, Monograph Review Staff, Office of OTC Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-210), 5600 Fishers Lane, Rockville, MD 20857, **301 295-8000**

RIN: 0905–AA06

1248. ABBREVIATED NEW DRUG APPLICATION REGULATIONS (TITLE I OF THE "DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984")

Significance:
Subject to OMB review: Undetermined

Legal Authority: 21 USC 355 title I

CFR Citation: 21 CFR 10; 21 CFR 310; 21 CFR 314; 21 CFR 320

Legal Deadline: None

Abstract: Until the passage of title I of the Drug Price Competition and Patent Term Restoration Act of 1984, abbreviated new drug application (ANDA) procedures were only available for generic products equivalent to pioneer drugs approved before 1962. Title I opened up the ANDA policy to generic copies of products approved after 1962. On July 10, 1989 (54 FR 28872), FDA proposed regulations to implement Title I. The proposal provides for the submission of abbreviated new drug applications for generic versions of drug products first approved after 1962. These new provisions will benefit consumers by making generic drug products available more quickly.

The agency is preparing the final rule in two segments. The final rule for the first segment, which establishes requirements for the format and content of an ANDA, suitability petitions, and certain administrative actions, published in the Federal Register of April 28, 1992 (57 FR 17950). The agency is reviewing the public comments submitted in response to the proposed requirements for patent certification and exclusivity and preparing a final rule on the segment.

Timetable:

Action	Date	FR Cite
NPRM	07/10/89	54 FR 28872
NPRM Comment Period End	10/10/89	54 FR 28872
NPRM Extension of Comment Period	10/11/89	54 FR 41629
NPRM Public Comment Period End	01/09/90	54 FR 41629
NPRM Extension of Comment Period	01/16/90	55 FR 1471
NPRM Public Comment Period End	04/09/90	55 FR 1471
Content and Format, Suitability Petitions		
Final Action	04/28/92	(57 FR 17950)
Patent Certification and Exclusivity		
Final Action	06/00/94	

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Philip L. Chao, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362),