

**Searched for: DERMAL**

**In document types: US LAW, US CFR, CURRENT EDITION, US FEDERAL REGISTER, US GUIDANCES, US LETTERS,**

**The search found 33 documents**

**Searched for: TOPICAL**

**In document types: US LAW, US CFR, CURRENT EDITION, US FEDERAL REGISTER, US GUIDANCES, US LETTERS,**

**The search found 191 documents**

## **US Federal Register**

- [16-JUL-2003](#) National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) Request for Existing Dermal and Ocular Irritancy Chemical Test Data From Animal and Human Studies Using Standardized Testing Methods
- [01-JUL-2003](#) National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health; Notice of Availability of Proposed Minimum Performance Standards (MPS) for Three Types of In vitro Methods for Assessing the Dermal Corrosivity Hazard Potential of Chemicals; Request for Comments
- [04-JUN-2003](#) Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph. 21 CFR Parts 310, 347, and 352
- [29-MAY-2003](#) Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph. 21 CFR Part 356
- [29-MAY-2001](#) Topical Antifungal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph. 21 CFR Part 333
- [08-AUG-2000](#) Listing of Color Additives Exempt From Certification; Luminescent Zinc Sulfide
- [21-MAY-1999](#) Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph

## US Federal Register

- [26-AUG-2003](#) Anorectal Drug Products for Over-the-Counter Human Use. 21 CFR Part 310
- [13-JUN-2003](#) Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule. 21 CFR Part 347
- [09-JUN-2003](#) Antiperspirant Drug Products For Over-the-Counter Human Use; Final Monograph. 21 CFR Parts 310, 350, and 369
- [04-JUN-2003](#) New Animal Drugs; Change of Sponsor
- [29-MAY-2003](#) Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-Care Antiseptic Drug Products; Reopening of the Administrative Record. 21 CFR Part 333
- [07-MAY-2003](#) Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use
- [19-DEC-2002](#) Bioavailability and Bioequivalence Requirements; Abbreviated Applications; Final Rule. 21 CFR Parts 314 and 320
- [17-MAY-2002](#) Draft Guidance for Industry on Topical Dermatological Drug Product NDAs and ANDAs-In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies; Withdrawal
- [05-APR-2002](#) Over-the-Counter Human Drugs; Labeling Requirements; Partial Delay of Compliance Dates. 21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701
- [15-MAR-2002](#) Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph. Correction. 21 CFR Part 333
- [08-FEB-2002](#) Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph. 21 CFR Part 333
- [23-JAN-2002](#) Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded. 21 CFR Part 330
- [29-AUG-2000](#) Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph
- [30-APR-1997](#) Sunscreen Drug Products for Over-the-Counter Human Use; Marketing Status of Products Containing Avobenzone; Enforcement Policy
- [15-NOV-1996](#) Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for OTC First Aid Antibiotic Drug Products

## US Guidances

- [01-DEC-2002](#) Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers. Draft. Guidance for Industry and Reviewers
- [01-JUL-1998](#) Developing Antimicrobial Drugs - General Considerations for Clinical Trials Guidance for Industry. Draft
- [01-JUL-1998](#) Uncomplicated and Complicated Skin and Skin Structure Infections – Developing Antimicrobial Drugs for Treatment Guidance for Industry. Draft
- [01-JUL-1998](#) Bacterial Vaginosis - Developing Antimicrobial Drugs for Treatment Guidance for Industry. Draft
- [01-JUL-1998](#) Vulvovaginal Candidiasis -Developing Antimicrobial Drugs for Treatment Guidance for Industry. Draft
- [01-JUN-1998](#) Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis). Guidance for Industry. Draft
- [17-FEB-1997](#) Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products. Guidance for Industry. Draft
- [16-OCT-1996](#) Points to Consider in the Nonclinical Pharmacology-Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases
- [22-JUL-1996](#) Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs
- [02-JUN-1995](#) Topical Dermatologic Corticosteroids: In Vivo Bioequivalence. Guidance
- [01-JUL-1994](#) Guide to Inspections of Topical Drug Products
- [24-FEB-1990](#) Performance of a Bioequivalence Study for Topical Antifungal Product. Guidance. Draft
- [01-MAY-1982](#) Guidelines for the Clinical Evaluation of Local Anesthetics

## US Letters

- [19-AUG-2003](#) Galderma Laboratories, L.P.
- [08-DEC-2000](#) Schering Corporation
- [13-MAR-2000](#) Glaxo Wellcome Inc. Warning Letter

**Searched for: DERMAL**

**In document types: ICH GUIDELINES,**

**The search found the following 5 documents**

**Searched for: TOPICAL**

**In document types: ICH GUIDELINES,**

**The search found the following 11 documents**

### **ICH Guidelines**

- [11-SEP-2002](#) M4S Common Technical Document for the Registration of Pharmaceuticals for Human Use: Safety Module 2: Nonclinical Overview and Nonclinical Summaries of Module 2 Organisation of Module 4
- [ICH M3](#) Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
- [08-NOV-2000](#) Safety Pharmacology Studies for Human Pharmaceuticals
- [16-JUL-1997](#) ICH S1B, Step 4: Testing for Carcinogenicity of Pharmaceuticals
- [29-NOV-1995](#) ICH S1A, Step 4: Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals
- [27-OCT-1994](#) ICH S3A, Step 4: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies

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**Searched for: DERMAL**

**In document types: EU REGULATIONS, EU DIRECTIVES,  
EU GUIDELINES**

**The search found the following 13 documents**

**Searched for: TOPICAL**

**In document types: EU REGULATIONS, EU DIRECTIVES,  
EU GUIDELINES**

**The search found the following 29 documents**

## **EU Directives**

[14-JUL-1997](#) 97/45/EC Adapting to Technical Progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the Approximation of the Laws of the Member States Relating to Cosmetic Products. 21st Commission Directive

## **EU Guidelines**

[20-NOV-2003](#) CPMP/EWP/2454/02 Clinical Investigation of Medicinal Products Indicated for the Treatment of Psoriasis. Note for Guidance

[27-JUN-2002](#) CPMP/SWP/398/01 Photosafety Testing

[26-JUL-2001](#) CPMP/EWP/QWP/1401/98. The Investigation of Bioavailability and Bioequivalence. Note for Guidance

[01-MAR-2001](#) CPMP/SWP/2145/00: Non-clinical Local Tolerance Testing of Medicinal Products. Note for Guidance

[01-FEB-1987](#) Clinical Investigation of Corticosteroids intended for Use on the Skin

[22-MAY-2003](#) CPMP/EWP/558/95 Rev.1/Draft Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections. Note For Guidance

[01-APR-1997](#) Evaluation of New Anti-Bacterial Medicinal Products. Note for Guidance

[01-NOV-1989](#) Summary of Product Characteristics for Antibacterial Medicinal Products

[01-FEB-1987](#) Clinical Investigation of Corticosteroids intended for Use on the Skin

[01-JAN-1987](#) Pharmacokinetic Studies in Man