

identification of other categories of OTC drug products that were in the marketplace when the OTC drug review began on May 11, 1972, or that were marketed before December 4, 1975, and describes FDA's general regulatory policy governing the marketing of these OTC drug products during the pendency of this review.

DATES: Submit data, information, and general comments by June 28, 2004.

ADDRESSES: Submit data and information directly to the Division of OTC Drug Products (HFD-560), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit general comments in writing to the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronically to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Michael T. Benson or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In 1972, FDA established the OTC drug review to evaluate currently marketed OTC drug products. The final regulations in part 330 (21 CFR part 330) providing for the OTC drug review under 21 CFR 130.301 (recodified as § 330.10) were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). Since that time, FDA has published various calls for data inviting interested parties to submit data and information for the advisory review panels to review.¹ During the course of the OTC drug review, advisory review panels reviewed many of the categories of OTC drug products included in prior call-for-data notices but did not review every category because of resource limitations.² Table 1 of this document

lists the categories of OTC drug products reviewed by all 17 panels and FDA and several categories of products that were reviewed by FDA only.

TABLE 1.—CATEGORIES OF OTC DRUG PRODUCTS REVIEWED BY 17 PANELS AND/OR FDA

Acne/Alcohol
Anorectal
Antacid
Anthelmintic
Anticaries
Antidiarrheal
Antiemetic
Antiflatulent
Antifungal:
 Diaper Rash
 Nails and Scalp
Antimicrobial:
 Alcohols (topical)
 Antiseptics (First aid)
 Antiseptics (Health Care)
 Diaper Rash
 Mercurials
Antiperspirant
Aphrodisiac
Benign Prostatic Hypertrophy
Boil Treatment
Camphorated Oil
Category II/III Ingredients (Phase I)
Category II/III Ingredients (Phase II)
Category II/III Ingredients (Additional)
Cholecystokinetic
Corn/Callus Remover
Cold/Cough:
 Anticholinergic
 Antihistamine
 Antitussive
 Bronchodilator
 Expectorant
 Nasal Decongestant
Dandruff/Seborrhea/Psoriasis
Daytime Sedative
Deodorant (Internal)
Digestive Aid
Exocrine Pancreatic Insufficiency
External Analgesic:
 Diaper Rash
 Fever Blister/Cold Sore
 Insect Bites/Stings
 Male Genital Desensitizer
 Poison Ivy/Oak/Sumac
Fever Blister/Cold Sore (Internal)
Hair Grower/Loss
Hexachlorophene
Hormone (topical)
Hypo/Hyperphosphatemia
Ingrown Toenail Relief
Insect Repellent (Internal)
Internal Analgesic:
 Leg Muscle Cramps
 Malaria
 Overindulgence
Laxative
Menstrual
Nailbiting/Thumbsucking Deterrent
Nighttime Sleep-aid
Ophthalmic
Oral Health Care:
 Antiseptic
 Non-Antimicrobial
 Oral Discomfort (Relief)
 Oral Mucosal Injury

TABLE 1.—CATEGORIES OF OTC DRUG PRODUCTS REVIEWED BY 17 PANELS AND/OR FDA—Continued

Oral Wound Healing
Plaque
Otic:
 Drying Water-Clogged Ears
 Earwax Removal
 Swimmer's Ear
Overindulgence Remedies:
 Prevent Inebriation
Pediculicide
Poison Treatment:
 Acute Toxic Ingestion Treatment
 Emetic
Salicylanilides (Tribromsalan)
Silver
Skin Bleaching
Skin Protectant:
 Astringent
 Diaper Rash
 Fever Blister/Cold Sore
 Insect Bites/Stings
 Poison Ivy/Oak/Sumac
Smoking Deterrent
Stimulant
Stomach Acidifier
Sunscreen
Sweet Spirits of Nitre
Vaginal Contraceptive
Vaginal Drug Products
Vitamin/Mineral
Wart Remover
Weight Control
Zirconium (Aerosol)

II. The Current Request for Data and Information

To complete the OTC drug review, FDA is publishing this call-for-data notice on the following categories of ingredients: (1) Nasal moisturizer drug products, (2) urinary analgesic/antiseptic drug products, (3) urinary acidifiers and alkalizers, (4) aloe vera and urea, (5) wrinkle remover products, and (6) lubricants and vaginal moisturizers. The categories of OTC drugs in this notice include some of the categories from the 1973 and 1975 notices that were not reviewed and several other categories that the agency has identified that were never reviewed. These include urinary analgesics/antiseptics and saline nasal products. Interested parties who identify other categories of OTC drug products that were in the marketplace when the OTC drug review began on May 11, 1972, or that were marketed before December 4, 1975 (see § 330.13), should submit comments regarding this document to the agency about those categories of OTC drug products, including the active ingredients in the products and the uses for which the products were marketed. Product labels should be provided if available.

¹See 38 FR 31696, November 16, 1973, and 40 FR 38179, August 27, 1975.

²FDA also identified several categories of marketed OTC drug products that were not reviewed by the advisory panels and publish subsequent call-for-data notices for those product categories. In the **Federal Register** of December 5, 1989 (54 FR 50240), FDA published a request for data and information on ingredients in eyewash drug products used for emergency first aid treatment of chemical burns of the eyes. FDA published a proposed rule for those products in the **Federal Register** of September 19, 1990 (55 FR 38560), FDA published a request for data and information on ingredients contained in products bearing antiplaque and antiplaque-related claims. The Dental Products Panel completed its review of the data and information that were submitted, and FDA published the panel's report in the **Federal Register** of May 29, 2003 (68 FR 32232).