DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 333

[Docket No. 80N-0476]

Topical Antifungal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; and Reopening of Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking and reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) topical antifungal drug products used for the treatment of diaper rash are generally recognized as safe and effective and not misbranded. This notice relates to the development of a monograph for topical antifungal drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC topical antifungal drug products to allow for consideration of a statement on drug products for the treatment of diaper rash that has been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Written comments by December 6, 1982 and reply comments by January 5, 1983.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on December 14, 1980 a statement from the Advisory Review Panel on OTC Miscellaneous External Drug Products relating to OTC drug products intended for use in the treatment of diaper rash. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing (1) the monograph recommended by the Panel, which establishes conditions under which these OTC drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

Because some ingredients in drug products for the treatment of diaper rash are marketed in OTC drug products for topical antifungal use, FDA has determined that the Miscellaneous External Panel's recommendations on OTC drug products for the treatment of diaper rash should be included as part of the proposed rulemaking for topical antifungal drug products. Development of this rulemaking has been ongoing for some time.

In the **Federal Register** of March 23, 1982 (47 FR 12480), FDA issued an advance notice of proposed rulemaking to establish a monograph for OTC topical antifungal drug products. FDA advises that it is reopening the administrative record for OTC topical antifungal drug products only as it pertains to drug products for the treatment of diaper rash in order to allow for the consideration of the Miscellaneous External Panel's recommendations on these products. Comments received on this advance notice of proposed rulemaking will be addressed in a future issue of the **Federal Register**. Also, the proceeding to develop a monograph for drug products for the treatment of diaper rash will be merged with the general proceeding to establish a monograph for OTC topical antifungal drug products.

The Panel did not recommend any Category I conditions for topical antifungal ingredients contained in drug products for the treatment of diaper rash. Therefore, no new sections to Subpart C of Part 333 (as set forth in the advance notice of proposed rulemaking that was published in the **Federal Register** of March 23, 1982 (47 FR 12480)) are included in this advance notice of proposed rulemaking for this drug category.

The unaltered statement of the Panel relating to OTC topical antifungal ingredients contained in products for the treatment of diaper rash is issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The statement has been prepared independently of FDA, and the agency has not yet fully evaluated the Panel's recommendations. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's statement. This statement represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC topical antifungal drug products, to include drug products for the treatment of diaper rash. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC topical antifungal drug products will be stated when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered in the amended notice of proposed rulemaking. At that time FDA also will consider whether the proposed rule as a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742).

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical antifungal drug products used for the treatment of diaper rash. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on topical antifungal drug products for the treatment of diaper rash should be accompanied by appropriate documentation. Comments will not be accepted at this time on any portion of the OTC topical antifungal rulemaking other than that relating to drug products for the treatment of diaper rash.

In accordance with § 330.10(a) (2), the Panel and FDA have held as confidential all information concerning

OTC drug products for the treatment of diaper rash submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after October 7, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureaus of Drugs and Biologics (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. In some advance notices of proposed rulemaking previously published in the OTC drug review, the agency suggested an earlier effective date. However, as explained in the tentative final monograph for OTC topical antimicrobial drug products (published in the **Federal Register** of July 9, 1982; 47 FR 29986), the agency has concluded that, generally, it is more reasonable to have a final monograph be effective 12 months after the date of its publication in the **Federal Register**. This period of time should enable manufacturers to reformulate, relabel, or take other steps to comply with a new monograph with a minimum disruption of the marketplace thereby reducing economic loss and ensuring that consumers have continued access to safe and effective drug products.

On or after the effective date of the monograph, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.'") In the **Federal Register** of August 27, 1975 (40 FR 38179), a notice supplemented the original notice with a detailed, but not necessarily all-inclusive, list of ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included "baby cream (diaper rash, rash, prickly heat)" active ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973 and August 27, 1975 informed OTC drug product manufacturers of their opportunity to submit data to the review at those times and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a)(1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman
Rose Dagirmanjian, Ph.D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by

John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R. Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents in this statement its conclusions and recommendations on OTC drug products containing topical antifungal ingredients for the treatment of diaper rash. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings at which drug products for the treatment of diaper rash were discussed were held on November 12 and 13, 1976; June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss topical antifungal ingredients contained in drug products for the treatment of diaper rash, nor was any individual requested to appear by the Panel.

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 14, 1980 in arriving at its conclusions and recommendations.

Referenced OTC Volumes

The "OTC Volumes" cited in this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after October 7, 1982 in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Statement on OTC Drug Products for the Treatment of Diaper Rash

A. Submissions of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as baby cream (diaper rash, rash, prickly heat) active ingredients. Fifty ingredients were identified as follows: alkyldimethyl benzylammonium chloride, allantoin (5-ureidohydantoin), aluminum acetate, aluminum hydroxide, amylum, balsam peru, benzethonium chloride, benzocaine, bicarbonate of soda, bismuth subnitrate, boric acid, calamine, calcium carbonate, camphor, casein, cod liver oil, cysteine hydrochloride, dibucaine, diperodon hydrochloride, glycerin, hexachlorophene, 8-hydroxyquinoline, iron oxide, lanolin, menthol, methapyrilene, methionine, methylbenzethonium chloride, oil of eucalyptus, oil of lavender, oil of peppermint, oil of white thyme, panthenol, *para*-chloromercuriphenol, petrolatum, phenol, pramoxine hydrochloride, salicylic acid, silicone, sorbitan monostearate, talc, tetracaine, vitamin A, vitamin A palmitate, vitamin D, vitamin D_2, vitamin E, white petrolatum, zinc oxide, and zinc stearate. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC drug products for the treatment of diaper rash.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Block Drug Co., Inc., Jersey City, NJ 07302..	Tashan Super Skin Cream.
Bristol-Myers Co., New York, NY 10022..	Ammens Powder.
Chesebrough-Pond's, Inc., Trumbull, CT 06611..	Vaseline Pure Petroleum Jelly.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927..	Aveeno Colloidal Oatmeal.
Corona Manufacturing Co., Atlanta, GA 30301..	Corona Ointment.
Macsil, Inc., Philadelphia, PA 19125..	Balmex Ointment.
Miles Laboratories, Inc., Elkhart, IN 46514..	Acid Mantle Creme, Acid Mantle Lotion.
Pennwalt Corp., Rochester, NY 14603..	Caldesene Powder, Caldesene Ointment, Proposed product containing Calcium Undecylenate and Hydrocortisone Acetate.
Pfizer Pharmaceuticals, New York, NY 10017..	Desitin Ointment.
Resinol Chemical Co., Baltimore, MD 21201..	Resinol Ointment, Resinol Greaseless Cream.
Sterling Drug, Inc., New York, NY 10016..	Diaparene Ointment, Diaparene Peri Anal, Diaparene Baby Lotion, Diaparene Medicated Baby Powder, Diaparene Diaper Rinse Solution, Diaparene Diaper Rinse (Tablets), Diaparene Diaper Rinse (Granules).
Stiefel Laboratories, Inc., Oak Hill, NY 12460..	Zeasorb Super Absorbent Medicated Powder.
Syntex Laboratories, Inc., Palo Alto, CA 94304..	Methakote Diaper Rash Cream.
The Upjohn Co., Kalamazoo, MI 49001..	Colcream Skin Cream.
USV Pharmaceutical Corp., Tuckahoe, NY 10707..	Panthoderm Cream, Panthoderm Lotion.
Whitehall Laboratories, Inc., New York, NY 10017..	Sperti Healing Ointment.
Warren-Teed Pharmaceuticals, Inc., Columbus, OH 43215..	Taloin diaper Rash Ointment.

2. *Related submissions.* The Panel received data on the role of corn starch as a nutrient for *Candida albicans* from the Department of Dermatology, University of Pennsylvania. Data on the safety of 100 percent corn starch as a dusting powder and an evaluation of the effectiveness of methylbenzethonium chloride in diaper rash remedies were received from Glenbrook Laboratories (a Division of Sterling Drug, Inc.).

3. *Ingredients.* The following list contains ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alkyldimethyl benzylammonium chloride
Allantoin (5-ureidohydantoin)
Aluminum acetate
Aluminum hydroxide
Aluminum dihydroxy allantoinate
Amylum
Aromatic oils
Balsam peru
Balsam peru oil
Beeswax
Benzethonium chloride
Benzocaine
Bicarbonate of soda
Bismuth subcarbonate
Bismuth subnitrate
Boric acid
Calamine (prepared calamine)
Calcium carbonate
Calcium undecylenate
Camphor
Casein
Cellulose
Chloroxylenol (*p*-cholo-*m*-xylenol)
Cod liver oil
Corn starch
Cysteine hydrochloride
Dexpanthenol (*D*-panthenol)
Dibucaine
Diperodon hydrochloride
Eucalyptol
Glycerin
Hexachlorophene
Hydrocortisone acetate
8-Hydroxyquinoline
Iron oxide

Lanolin
Live yeast cell derivative
Magnesium carbonate
Menthol
Methapyrilene
Methionine
DL-Methionine
Methlybenzethonium chloride
Microporous cellulose
Mineral oil
Oil of cade
Oil of eucalyptus
Oil of lavender
Oil of peppermint
Oil of white thyme
Panthenol
Para-chloromercuriphenol
Petrolatum
Phenol
Phenylmercuric nitrate
Pramoxine hydrochloride
Protein hydrolysate (composed of *L*-leucine, *L*-isoleucine, *L*-methionine, *L*-phenylalanine, and *L*-tyrosine)
Resorcinol (resorcin)
Salicylic acid
Shark liver oil
Silicone
Sorbitan monostearate
Starch
Talc
Tetracaine
Vitamin A
Vitamin A palmitate
Vitamin D
Vitamin D_2
Vitamin E (*DL-alpha*-tocopheryl acetate))
White petrolatum
Zinc oxide
Zinc stearate

B. General Discussion

The Panel has determined that many of the ingredients contained in products with "diaper rash" claims submitted to this Panel (Ref. 1), or labeling claims related to diaper rash (skin irritation), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of diaper rash.

In the **Federal Register** of March 23, 1982 (47 FR 12480), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC topical antifungal drug products. The OTC drug products subject to this rulemaking include products used for the treatment of athlete's foot, ringworm, jock itch, and the control of *Candida*. The Miscellaneous External Panel believes that the use of these products to control fungus may prevent further skin irritation associated with diaper rash. Furthermore, the Panel notes that benzethonium chloride, boric acid, calcium undecylenate, camphor, chloroxylenol, (*p*-chloro-*m*-xylenol), 8-hydroxyquinoline, menthol, phenol, resorcinol (resorcin), and salicylic acid are included in the antifungal rulemaking and therefore recommends that the use of these ingredients for "diaper rash" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA considers most appropriate. (Note: In order to assure that these ingredients are referred to the most appropriate rulemakings, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.) The Panel also recommends that FDA develop labeling for diaper rash drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "diaper rash." (Note: Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of diaper rash is included in the rulemakings for topical antimicrobial drug products, external analgesic drug products, and skin protectant drug products.)

The Panel further notes that hexachlorophene is included in the above list of ingredients. However, the use of hexachlorophene as a component of OTC drug products is restricted by 21 CFR 250.250(d). Hexachlorophene is limited to situations where an alternative preservative has not yet been shown to be as effective or where aedquate integrity and stability data for the reformulated product are not yet available. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application.

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC diaper rash drug products.

Diaper rash is a common skin problem of infancy, caused by contact with urine and feces, worsened by occlusion with plastic pants, and often secondarily infected with *Candida albicans*. It has an excellent prognosis for permanent cure after an infant is toilet trained. Incontinent adults may get similar irritant contact dermatitis.

The skin under the diaper is macerated by prolonged wetness. Disposable diapers with a plastic backing, or plastic pants used over regular diapers, keep heat as well as moisture in, causing miliaria (prickly heat) as well as more maceration than occurs with the use of regular diapers alone. Bacteria proliferate in this warm, moist environment, thriving on nutrients in feces and metabolizing urine to produce ammonia, an irritant. *Candida albicans*, often present in feces, also proliferates to produce a characteristic bright red, sharply marginated rash with satellite pustules and erosions. Other exacerbating factors are mechanical irritation (chafing) from rough cloth or tight or stiff plastic, chemical irritation from detergent and bleach in diapers or from soap used to cleanse the baby, diarrhea, and heat.

Ordinary mild diaper rash, characterized by erythema of the buttocks, perineum, and lower abdomen, responds to very frequent diaper changes, cleansing with water, and removal of plastic occlusion (switching to cloth diapers, often two at the same time). Most treatments help by protecting the skin, acting as a physical barrier to irritants, and absorbing or absorbing moisture. Examples are talc and zinc oxide ointment and paste.

The Panel wishes to point out that physicians treat severe diaper rash with topical antifungal and anticandidal drugs such as iodochlorhydroxyquin, nystatin, amphotericin B, miconazole nitrate, and clotrimazole, often in combination with a topical steroid (Refs. 2 and 3). Potent fluorinated steroids, such as 0.1 percent triamcinolone cream, should not be used on diaper rash because, when applied under occlusive dressings, these steroids can produce local thinning of the skin, with striae and easy bruising, but 0.5 to 1 percent hydrocortisone cream is recommended.

References

(1) OTC Volumes 160021, 160025, 160027, 160028, 160038, 160040, 160041, 160042, 160053, 160067, 160069, 160070, 160077, 160088, 160091, 160104, 160204, 160236, 160242 through 160247, 160271, 160272, 160277, 160357, 160362, and 160427.

(2) Weston, W. L., "Practical Pediatric Dermatology," Little, Brown and Co., Boston, pp. 51–53, 1979.

(3) Weinberg, S., and R. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," McGraw Hill, New York, p. 121, 1979.

Interested persons may, on or before December 6, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600

Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before January 5, 1983. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs.

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: August 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24424 Filed 9-3-82; 8:45 am]

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