MEETING OF THE PANEL ON REVIEW OF
MISCELLANEOUS EXTERNAL OTC DRUG PRODUCTS

Twenty-third Meeting
January 29 and 30, 1978

Parklawn Building
Rockville, Maryland

and

Holiday Inn
Bethesda, Maryland

Panel Members

William E. Lotterhos, M.D.
Chairman
Chester L. Rossi, D.P.M.
Rose Dagirmanjian, Ph.D. (absent)
Harry E. Morton, Sc.D.
George C. Cypress, Jr., M.D.
Marianne N. O'Donoghue, M.D.
Yelva L. Lynfield, M.D.

Consultants
A. Belmonte, Ph.D.
Jon Tanja, R.Ph.

Liaison Representatives

Consumer Liaison (C.U.)
Marvin M. Lipman, M.D.

Industry Liaison
Bruce Semple, M.D.
Saul A. Bell, Pharm.D. (CTFA)

FDA Members

John T. McElroy, J.D. - Panel Administrator
Arthur E. Auer, B.Sc. - Executive Secretary (absent)
Victor Lindmark, Pharm.D. - Drug Information Analyst
Acting Executive Secretary

Statements made herein are provisional in nature and may be modified or revised in subsequent meetings of the Panel or in their final complete report to the Commissioner.

Whenever there is a lack of unanimity on any given point, the vote will be given. Regulations do not permit voting by the Liaison Members, Consultants, or FDA Staff Members.

Adopted 16 April, 1978

William E. Lotterhos, M.D.
Chairman

81N.0144

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SUMMARY OF PANEL ACTION OF THE
23rd MEETING

Ingredients	Concentration Range	Indications	Categorization
estrogenic substances	10,000 IU/oz and less	skin moisturizer	I (S), II (E)
progesterone	5 mg/oz and less	skin moisturizer	I (S), II (E)
colloidal oatmeal	all concentrations	antipruritic	I (S + E)
borates sodium borate borax boric acid	all concentrations		II (S)
benzoic acid	all concentrations	keratolytic fungicide	I (S), II (E) I (S), III (E)
coal tar gels		psoriasis	I (E), III (S)
collodion preparations collodion USP flexible collodion USP	all concentrations	skin protectant	I (S + E)
chlorophyllins	all concentrations	antipruritic wound healing wound deoderant	I (S), III (E) I (S), III (E) I (S), III (E)

(S) = safety
(E) = efficacy

GUESTS IN ATTENDANCE.

David Miller, Consultant

Pat Dsida, Westwood Pharmacueticals

John Gwinner, Proctor & Gamble

INDUSTRY PRESENTATIONS TO THE PANEL.

None.

CONSIDERATION OF SUMMARY MINUTES.

The minutes of the 22nd meeting of the Panel (December 11 and 12, 1977) were read and approved. The Proprietary Association liaison informed the Panel of industry's concern over the categorization of salicylic acid at the 22nd meeting of the Panel, i.e., the Category III (safety) determination. Industry wishes to know the rationale for the determination and what kind of data and information the Panel requires for a Category I judgement. Guidelines for testing will be specified at a future meeting and further discussion of the issue was tabled.

UNFINISHED BUSINESS.

Denatonium benozate. The Panel continued its discussion of the effectiveness of denatonium benzoate as a thumb-sucking/nail biting deterrent. Because of the lack of any kind of data documenting effectiveness, the Panel voted that it remain in Category III. (Denatonium benzoate's Category III status with respect to safety remains unchanged.)

A discussion of the types of testing protocols that might be used for a determination of efficacy ensued. The Panel voted that some sort of

efficacy testing would be required. However, guidelines for this testing will be specified at a future meeting.

Karaya/gum tragacanth mucilage. This preparation is found in an aerosol (spray-on bandage) drug product. Discussion was deferred until it was decided whether the Panel or the Bureau of Medical Devices would handle this preparation. The OTC staff was asked to look into this matter.

NEW BUSINESS.

Ingredients not submitted to the Panel. The following ingredients, although listed in the call-for-data for foot care products (40 FR 38179), were not found in the foot care product ingredients submitted to the Panel for review:

alkaloids of belladonna

amyl salicylate

beeswax

benzalkonium chloride

camphor gum

ether

methylbenzethonium chloride

methyl salicylate

sodium carbonate

sassafras oil

parachlorometaxylenol (PCMX)

pyroxyllin

vitamin A acid (retinoic acid)

The Panel tentatively, by a vote of 5 to 1, declared these ingredients to be inactive with respect to foot-care products.

Female hormones.

a. Estrogens. Because of the current concern over the use of estrogens, the Panel reviewed their use in non-prescription drugs and cosmetics. Because of the known pharmacological effects of these agents, the Panel classifies all products containing them to be drugs. Although it is known that estrogens are readily absorbed percutaneously, the Panel felt that at the low concentrations used, the products are safe at a concentrations of up to and including 10,000 I.U. per ounce. The Panel was unable to find any data to document effectiveness and has placed estrogens in Category II.

b. Progesterone. Because of the known pharmacological effects of this agent, the Panel classifies all products containing progesterone to be drugs. Progesterone was placed in Category I for safety and Category II for effectiveness at concentrations of up to and including 5 mg per ounce.

The female hormones in the products submitted are obtained from gravid mare's urine. The consumer liaison informed the Panel that non-pre-

scription products containing placental hormone extracts are also being marketed. The consumer liaison will document this further.

Colloidal oatmeal. The Panel reviewed the antipruritic claims of colloidal oatmeal as used in bath additives, cleansing bars and soaks. By a vote of 5 to 1 the Panel found colloidal oatmeal, at all concentrations, to be safe and efficacious for "the symptomatic relief and treatment of itching".

Borates (sodium borate, borax and boric acid). The Panel reaffirmed its earlier conclusion that borates are ineffective and unsafe at all concentrations. Boric acid is reported to be more toxic to cells in-vitro than most other ingredients of its class (Everett, Pomerat, Hu and Livingood "Tissue Culture Studies on Human Skin. I. A Method of Evaluating the Toxicity of Certain Drugs Employed Locally on the Skin," Texas Reports on Biology and Medicine, 9:281-291, 1951.) Boric acid is often used as a buffering agent (pharmaceutical aid). The Panel feels that safer, less toxic buffering agents should be used and that boric acid should be totally removed from all miscellaneous external OTC drug products.

Benzoic acid. The Panel discussed a report on benzoic acid. A thorough review of the literature and submissions indicates that benzoic acid is not absorbed percutaneously, perhaps due to its insolubility. The Panel recognizes the possibility of allergic reactions paritcularly among

people who are allergic to compounds containing benzyl or acetyl groups. The Panel voted to place benzoic acid in Category I for safety at all concentrations. Efficacy of benzoic acid was evaluated with respect to two claims; keratolytic and fungicidal. The Panel placed benzoic acid in Category III as an antifungal. To prove efficacy as an antifungal agent, fungicidal activity should be demonstrated with benzoic acid alone and not in combination with other active ingredients. As a keratolytic, benzoic acid was placed in Category II for efficacy. Further, the Panel recommended a label warning contraindicating the use of benzoic acid by people who are sensitive to aspirin.

Coal tar preparations. The Panel discussed a letter sent to them by a practicing dermatologist recommending that coal tar preparations be limited to prescription use because of the danger of skin cancer. The Panel, based on information obtained from the Coal Tar Symposium (19th meeting of the Panel) and its own clinical experience, believes that coal tar preparations can be safely used on a non-prescription basis. However, all coal tar preparations are contraindicated for use in the groin, genital, and anal areas.

Crude coal tar. The Panel reaffirmed its previous position that crude coal tar be placed in Category I for effectiveness and Category III for safety, pending the results of a retrospective study at the Mayo Clinic to determine the incidence of neoplasia.

Coal tar gels. The Panel found coal tar gels to be Category I for effectiveness and Category III for safety, pending the outcome of the Mayo Clinic study. With respect to relative effectiveness, the Panel noted that the coal tar gels are less effective than crude coal tar.

Collodion preparations (collodion USP, and flexible collodion USP). Due to the wide clinical experience and the absence of reported toxicity, the Panel believes that collodion USP, and flexible collodion USP are both safe and effective. The Panel placed collodion USP, and flexible collodion USP in Category I for safety and effectiveness for use as an occlusive bandage.

The consumer liaison raised the question of potential inhalational abuse of the ether contained in collodion preparations. The Panel decided that this aspect is better covered by the Consumer Product Safety Commission.

Trisodium phosphate. After a thorough search of the submissions, it was discovered that trisodium phosphate is not used in any of the foot care products submitted to the Panel. A report was prepared and accepted for information pending a determination by the Agency of what to do with any ingredients in the Call-for-Data for which no submissions have been received.

Chlorophyllins. This group of compounds consists mostly of the copper complex of sodium and/or potassium salts of saponified chlorophyll. The

Panel found chlorophyllins safe for topical use at all concentrations. Three claims are made for the chlorophyllins:

antipruritic

wound healing accelerator

wound deodorant

The Panel voted (4 to 1) to place antipruritic claims in Category III recommending a controlled double-blind study of the chlorophyll preparation against the vehicle itself. The Panel also voted (4 to 1) to place wound healing accelerator claims in Category III. The Panel will consider testing guidelines for wound healing claims adopted by the Antimicrobial I Panel before specifying further guidelines for this claim.

The Panel took note of the Oral Cavity Panel's action on chlorophyll, i.e., that chlorophyll is safe at all concentrations but that it is Category II for effectiveness for use as a wound healing accelerator for use on the oral and pharyngeal mucosa.

The Panel considers wound deodorizing claims to be a therapeutic claim and placed the chlorophyllins in Category III for that purpose. Again, a double-blind study of the chlorophyllin against the vehicle is required.

The Panel discussed a statement of its policy (Addendum A) with respect to Category II and Category III conditions.

MEETING OF THE PANEL ON REVIEW OF
MISCELLANEOUS EXTERNAL OTC DRUG PRODUCTS
Forty-Second Meeting
November 7 and 8, 1980

Parklawn Building
Rockville, Maryland
and
Holiday Inn
Bethesda, Maryland

Panel Members

William E. Lotterhos, M.D.
Chairman
Rose Dagirmanjian, Ph. D.
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Yelva L. Lynfield, M.D.
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Tom McGinnis, R.Ph. - Drug Information Specialist
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14 Dec. 1980
Adopted

W. E. Lotterhos MD
William E. Lotterhos, M.D.
Chairman

SUMMARY MINUTES

The meeting was called to order on November 7, 1980 at 9:00 a.m.

Presentations

1. Miles Laboratories, Inc., John F. Britto, M.D. and James Leyden, M.D.--discussed the efficacy of "Aluminum Acetate (Burow's Solution)" as compared to water in the treatment of poison ivy eruptions.

2. Joint Industry Coal Tar Committee - "Update and Review of Coal Tar," Richard C. Brogle, Ph. D., Chairman. A literature review of the safety of coal tar was presented to the Panel.

3. Westwood Pharmaceuticals Inc., William H. Hubregs, Ph. D. and James Leyden, M.D.--"Effectiveness of Sulfur 2 percent-Salicylic Acid 2 percent in a Dandruff Shampoo." Results of a study conducted by James Leyden on the use of sulfur 2 percent alone, salicylic acid 2 percent alone, and the combination of sulfur 2 percent and salicylic acid 2 percent were presented to the Panel.

4. Helene Curtis, Inc., Norman Meltzer, Ph. D. and Mr. Stephen Schwartz--"Effectiveness of Sulfur in a Dandruff Shampoo." Effectiveness data on sulfur in a shampoo base were presented to the Panel.

5. Plough Inc., Kenneth Johannes--"Safety and Effectiveness of Epinephrine Hydrochloride As An OTC Topical Hemostat." Data on a proposed skin wound cleanser and topical hemostat combination were presented to the Panel.

Response to Panel announcement that submissions would not be received after C.O.B. November 7-8, 1980.

The following information was received and acknowleged by the Panel:

1. Aloe Vera of America's protocol for aloe in ". . . The Treatment of Inflammatory and Pruritic Disorders of the Skin."

2. Glenbrook Laboratories - "Safety Evaluation of 100 percent Cornstarch as a Dusting Powder," and "Efficacy of Methylbenzethonium in the Treatment of Diaper Rash."

3. Letter dated October 21, 1980 from Saul A. Bell, Pharm. D., Industry Liaison to the OTC Miscellaneous External Panel, listing unfinished Panel business.

4. Letter dated November 6, 1980 from Norman Estrin, Ph. D., The Cosmetic, Toiletry and Fragrance Association, Inc., requesting a delay in disbanding the OTC Miscellaneous External Panel.

5. Letter of November 6, 1980 to the Panel Administrator requesting distribution to Panel members of a letter dated November 6, 1980 to J. Richard Crout, M.D. expressing concern over the disbanding of the OTC Miscellaneous External Panel at the end of 1980.

Open Panel Discussion and Action

1. Dandruff, Seborrheic Dermatitis, and Psoriasis Report.

Ingredients

Boric acid--0.5 percent--The Panel defeated a motion to move boric acid from Category II to Category III for the treatment of dandruff, seborrheic dermatitis, and psoriasis. (4 against the motion, 3 abstentions)

Coal tar--The Panel recommended that the agency move to standardize coal tar fractions and the nomenclature of coal tar fractions. Coal tar is Category I for use on the scalp and Category III for use on the body.

Coal tar in combination with allantoin was placed in Category III.

Cresol--The Panel agreed to leave cresol shampoos in Category II for effectiveness in dandruff, seborrheic dermatitis, and psoriasis.

Hydrocortisone--The Panel agreed that hydrocortisone for OTC use was Category I for safety in concentrations less than 0.5 percent. In concentrations of 0.5 - 1.0 percent hydrocortisone was placed in Category III for safety and effectiveness in the treatment of seborrheic dermatitis and

psoriasis of the scalp. Coal tar in combination with hydrocortisone was placed in Category III.

Juniper tar and Pine tar--both were reclassified from Category I to Category III for effectiveness. The Panel recommends that further appropriate studies be run for these ingredients.

Pyrithione zinc--1 and 2 percent--in a shampoo for control of symptoms of dandruff and seborrheic dermatitis and 0.1 - 0.25 percent in a hair dressing for control of symptoms of dandruff and seborrheic dermatitis remain in Category I for safety and effectiveness.

Resorcinol--was placed in Category II for effectiveness because of no available data before the Panel for its use on the scalp as a keratolytic for seborrheic dermatitis, or for psoriasis.

Salicylic acid--1.8 - 3.0 percent--was classified as Category I for safety and effectiveness for dandruff and seborrheic dermatitis of the scalp. The Panel approved a concentration of 1.8 - 3.0 percent in a shampoo rinse or rinse off vehicle for control of symptoms of dandruff, seborrheic dermatitis, and psoriasis of the scalp. For topical (body use other than scalp) a concentration of 1.8 - 3.0 percent salicylic acid may be used up to 4 times daily for symptoms of seborrheic dermatitis, and psoriasis.

Salicylic acid/Sulfur combination--The combination of salicylic acid 2 - 3 percent and sulfur 2 - 5 percent was placed in Category I for safety and effectiveness for dandruff and seborrheic dermatitis.

Selenium sulfide--1 percent was classified as Category III for effectiveness when used in the treatment of seborrheic dermatitis.

Sulfur--2 - 5 percent was classified as Category I for safety and effectiveness in the treatment of dandruff.

Labeling

Creams for body psoriasis and seborrheic dermatitis--Panel recommended that these preparations be labeled for use 1 to 4 times a day.

Warning statement--Panel recommended that labeling for all OTC dandruff, seborrheic dermatitis, and psoriasis products bear the warning that if condition worsens or does not improve after regular use that the patient see a doctor.

The Panel approved a copy of its Dandruff, Seborrheic Dermatitis, and Psoriasis Report as an "information copy" for public display in FDA's Dockets Management Branch (formerly the Hearing Clerk's Office).

2. Diaper Rash Report--The Panel approved an "information copy" of its report for public display. The Panel agreed that ingredients for diaper rash are to be handled in other OTC rulemaking procedures.

3. OTC Boil Ointment Report--The Panel approved an "information copy" of its report for public display.

4. Fever Blister Report--Subject to revisions to be made by two Panel members, the Panel approved an "information copy" of its report for public display.

5. OTC Insect Bite Neutralizer Drug Products Report--The Panel approved an "information copy" of its report for public display.

6. Poison Ivy Prevention Report--The Panel approved an "information copy" of its report for public display.

7. Astringent Report--The Panel approved an "information" copy of its report for public display.

Aluminum acetate--(4.8 - 5.8 gms per 100 mL)--The Panel approved a motion to move from Category III to Category I a 1 in 20 dilution of aluminum acetate solution (Burow's Solution) as safe and effective for use as a wet dressing astringent. (4 in favor, 2 against, 1 abstention)

Aluminum sulfate--57 percent concentration in styptic pencil dosage form--was placed in Category I for safety when applied to the skin in small amounts (0.1 - 0.2 mL of a 57 percent concentration), and Category III for effectiveness as a styptic when present as 57 percent concentration of aluminum sulfate in a styptic pencil dosage form.

Sodium silicate, and magnesium aluminum silicate--for these ingredients, the following claims were considered by the

Panel to be cosmetic claims: smooths over "wrinkles" and "crows feet," "stretching of skin by physical action."

The Panel will refer these ingredients back to the agency for further disposition.

Witch hazel (hamamelis water)--was placed in Category III as a topical astringent.

8. Pediculicide Report--The Panel increased the concentration of piperonyl butoxide from 2 to 3 percent to 2 to 4 percent in the Category I combination of piperonyl butoxide and pyrethrins. The Panel also modified the indication section of its report.

The Panel approved an "information copy" of its report for public display.

9. Topically Applied Hormone Drug Products Report--The Panel added to its report additional data on the topical use of progesterone. The Panel approved an "information copy" of its report for public display.

10. Minutes--The Panel approved the minutes of its previous meeting October 5 and 6, 1980.

11. Next Meeting--The Panel scheduled its next and final meeting for December 14 and 15, 1980.

MEETING OF THE PANEL ON REVIEW OF
MISCELLANEOUS EXTERNAL OTC DRUG PRODUCTS
Forty-Third Meeting
December 14 and 15, 1980

Parklawn Building
Rockville, Maryland
and
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Bethesda, Maryland

Panel Members

William E. Lotterhos, M.D.
Chairman
Rose Dagirmanjian, Ph. D.
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Dec. 15 1980
Adopted

William E. Lotterhos, M.D.
Chairman

SUMMARY MINUTES

The meeting was called to order on Sunday, December 14, 1980 at 9:00 a.m. in the Pennsylvania Room of the Holiday Inn, Bethesda, Maryland and on Monday December 15, 1980 in Conference Room "C" of the Parklawn building, Rockville, Maryland.

Presentations

1. The Tender Corporation, presentation by Leon Freeman, Ph. D. on ammonium hydroxide for the treatment of insect bites.

2. E. E. Dickinson Company, a written presentation received from Richard Kirpes on Witch Hazel.

3. The National Psoriasis Foundation, presentation by Ms. Gail Zimmerman on the OTC use of coal tar for psoriasis.

4. The Proprietary Association, presentation by Richard Brogle, Ph. D. on the progress of the industry committee on coal tar.

5. Plough, Incorporated, presentation by Kenneth Johannes on labeling aspects of the dandruff report.

6. American Distilling and Manufacturing Company Incorporated, presentation by Edward Jackowitz on Witch Hazel.

7. Requa Manufacturing, presentation by Kenneth Klippel on aluminum sulfate in styptic pencils.

8. Beecham Products, a written presentation from Bernard Misek, Ph. D. requesting that the Panel defer to the OTC Contraceptive Panel matters relating to vaginal astringents.

9. Whitehall Laboratories, a written presentation citing the need for the continued availability of OTC coal tar drug preparations for the treatment of psoriasis.

Open Panel Discussion and Action

1. Dandruff, Seborrheic Dermatitis, and Psoriasis Report.

Coal tar--The Panel reaffirmed its position that coal tar for body use (other than scalp) is Category I for

effectiveness and Category III for safety. The Panel cited the need for long-term studies and continued work on the standardization of coal tar. The Panel firmly advocates that coal tar continue to be available for OTC use while the long term studies are being conducted.

Captan--The Panel expanded the range for captan (Category III) to include concentrations of 0.1 to 2.0 percent.

Products for control solely of dandruff--The Panel defeated a motion to remove the warning statement from dandruff products "if condition worsens or does not improve after regular use of this product as directed, consult a doctor." The motion failed to carry by a vote of 4 opposed and 3 in favor.

Panel report--The Panel adopted its Dandruff, Seborrheic Dermatitis, and Psoriasis report, as amended.

2. Diaper Rash Statement. The Panel adopted its Diaper Rash Statement. Ingredients reviewed by the Panel are to be transferred by the agency to other appropriate rulemakings in the OTC drug review.

3. OTC Boil Ointment Report. The Panel rejected the rationale of the use of OTC analgesics for the relief of pain as part of the OTC treatment of boils. The Panel was concerned that the use of an OTC topical analgesic may lead to a delay of professional treatment. The Panel reiterated its position that boils are not amenable to OTC treatment. The Panel adopted its Boil Ointment Report which concludes that any OTC boil treatment is Category II.

4. Fever Blister Statement. The Panel adopted its Fever Blister Statement. Ingredients reviewed by the Panel will be transferred by the agency to other appropriate rulemakings in the OTC drug review.

5. OTC Insect Bite and Sting Treatment Statement. The Panel changed the name of its "OTC Insect Bite Neutralizer Drug Products Report" to "OTC Insect Bite and Sting Treatment Statement."

Ammonium hydroxide--The Panel approved a motion that ammonium hydroxide (1 to 2.5 percent) be placed in Category III for the treatment of insect bites and stings. This motion was carried by a vote of 6 in favor and 1 opposed.

The Panel approved a motion to include in its report material presented by Leon Freeman, Ph. D., on behalf of the Tender Corporation, on ammonium hydroxide as related to treatment and neutralization of insect bites.

Triethanolamine--remains in Category III for the treatment of insect bites and stings.

The Panel adopted its Insect Bite and Sting Treatment Statement, as amended. The Panel referred back to the agency, for handling in other appropriate OTC drug rulemakings, claims for the treatment of insect bites and stings.

6. Poison Ivy, Oak, and Sumac Prevention Statement. The Panel adopted its Poison Ivy, Oak, and Sumac Prevention Statement. Ingredients reviewed by the Panel will be transferred by the agency to other appropriate rulemakings in the OTC drug review.

7. Astringent Statement.

Aluminum sulfate--The Panel approved a motion to move aluminum sulfate (57 percent) in a styptic pencil dosage form from Category III to Category I as a safe and effective astringent-styptic. This motion was carried by a vote of 5 in favor and 2 opposed.

The Panel adopted its Astringent Statement. Ingredients reviewed by the Panel will be transferred by the agency to other appropriate rulemakings in the OTC drug review.

8. Pediculicide Report.

Copper oleate--The Panel approved a motion to include in its report copper oleate as a Category II ingredient for safety and effectiveness. The Panel placed this ingredient in Category II because of a lack of data to show safety and effectiveness for the treatment of pediculosis.

Ovicidal claims--Data reviewed by the Panel for pyrethrin-piperonyl butoxide ovicidal activity did not show a 100 percent kill rate but only about 20 percent. Accordingly, the Panel approved a motion that an unqualified claim that a product is ovicidal is a Category II claim. This motion was carried by a vote of 6 in favor and 1 opposed.

The Panel approved a motion to adopt its Pediculicide Report, as amended.

9. Topically Applied Hormone Drug Products Report.

Estrogen--The Panel approved a motion to move estrogen (10,000 International Units) from Category I to Category III for safety. The vote was 6 in favor and 1 opposed. The Panel noted that the issue of safety may be mute, since all drug claims for OTC topical hormone preparations are Category II.

Progesterone--not exceeding 5 mg/oz remains in Category I for safety and Category II for effectiveness.

Hormones in cosmetics--The Panel unanimously approved the following statement: "The Panel recognizes an inherent fallacy in marketing a cosmetic containing a medication regardless of non-medical intention of the label claim. If such a medication affects the structure or function of the skin, then the purported cosmetic is, in fact, a medication. If the medication is present in such small quantities that neither the structure nor the function of the skin is altered, then its presence in the cosmetic is misleading, and the product should be considered misbranded."

The Panel voted that its document on topically applied hormone drug products be adopted as a report and not as a statement. The vote was 5 in favor and 2 opposed.

The Panel unanimously adopted its Topically Applied Hormone Drug Products Report, as amended.

10. Minutes. The Panel approved the minutes of its previous meeting November 7 and 8, 1980. The Panel Chairman approved the minutes of this meeting, December 14-15, 1980.

11. This was the final meeting of the Panel. The Panel Administrator expressed thanks to the Chairman and other individual Panel members, consultants, and liaisons for all of their contributions and hard work over the past 5 years.