

Complaint

IN THE MATTER OF

E. C. DEWITT & CO., INC.

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE
FEDERAL TRADE COMMISSION ACT*Docket 8642. Complaint, Aug. 28, 1964—Decision, Dec. 16, 1966**

Order requiring a New York City manufacturer of "Man Zan Pile Ointment" and other pile remedies to cease falsely representing in its advertising that its product will shrink, avoid need for surgical treatment on, heal, cure, or remove hemorrhoids or effect any other cure beyond temporary relief.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that E. C. DeWitt & Co., Inc., a corporation, hereinafter referred to as respondent has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent E. C. DeWitt & Co., Inc., is a corporation, organized, existing and doing business under the laws of the State of New York, with its principal office and place of business located at 730 Fifth Avenue, in the city of New York, State of New York.

PAR. 2. Respondent E. C. DeWitt & Co., Inc., is now and has been for more than one year last past, engaged in the sale and distribution of three preparations offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act.

The designations used by respondent E. C. DeWitt & Co., Inc., for said preparations, the formulas thereof and the directions for use are as follows:

A. *Designation*: "DeWitt's Stainless Man Zan Pile Ointment."

Formula: Active Ingredients: CARBOLIC ACID ½% BENZOCAINE, ZINC OXIDE, ALLANTOIN, EPHEDRINE HCl.

Directions: For palliative relief cleanse affected parts with warm water and toilet soap; dry with soft towel. After gently inserting the

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Stainless Man Zan applicator as far as possible into the rectum, squeeze tube to apply a liberal quantity. Use night and morning, also after stooling when convenient.

CAUTION: Avoid using this preparation in case of undue bleeding, since this may indicate a serious condition requiring medical advice.

B. *Designation: "Man Zan Pile Ointment."*

Formula: Active Ingredients: Ephedrine HCl Allantoin, Benzocaine Carbolic Acid 0.5% Menthol, Tannic Acid.

Directions: For palliative relief cleanse affected parts with warm water and toilet soap; dry with soft towel. After gently inserting the Man Zan applicator as far as possible into the rectum, squeeze tube to apply a liberal quantity. Use night and morning, also after stooling when convenient.

CAUTION: Avoid using this preparation in case of undue bleeding since this may indicate a condition requiring medical advice.

C. *Designation: "DeWitt's Stainless Man Zan Suppositories."*

Formula: Active Ingredients: Benzocaine Zinc Oxide, Phenol 0.5% Allantoin, Phenylpropanolamine.

Directions: Before using Man Zan Suppositories remove the protective foil wrapping. Wash affected parts, then insert the suppository as high as possible into the rectum. Use morning and night and after each bowel movement. Treatment should be continued daily for best results. External discomforts are best treated with Man Zan Pile Ointment—Stainless or Regular.

CAUTION: If relief is not obtained in a reasonable period of time, and in cases of undue bleeding, consult your physician.

PAR. 3. Respondent E. C. DeWitt & Co., Inc., causes the said preparations, when sold, to be transported from its place of business located at 2835 Sheffield Avenue, Chicago 14, Illinois, to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial.

PAR. 4. In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning the preparations referred to in Paragraph Two, above, by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to advertisements in newspapers, magazines and other advertising media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations; and has disseminated, and caused the dissemination of, advertisements concerning said preparations by various means,

including but not limited to the aforesaid media for the purpose of inducing and which were likely to induce, directly or indirectly the purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Among and typical of the statements and representations contained in said advertisements disseminated as hereinabove set forth are the following:

Itching and Soreness of hemorrhoid discomfort quickly relieved with DeWitt's Manzan. Manzan contains Allantoin for healing, benzocaine to ease pain, and a vasoconstrictor to help reduce swelling. For soothing action and fast palliative relief, try . . . Manzan ointment or Suppositories

HEMORRHOIDS Real Relief . . . When simple hemorrhoids cause agony . . .

. . . a special healing agent.

. . . to ease pain . . . reduce swelling.

REAL RELIEF FROM HEMORRHOIDS

. . . now even more effective with Allantoin, a special healing agent.

PAR. 6. Through the use of said advertisements and others similar thereto not specifically set out herein, respondent has represented and is now representing, directly and by implication that the use of DeWitt's Stainless Man Zan Pile Ointment, Man Zan Pile Ointment, DeWitt's Stainless Man Zan Suppositories, and each of them, will:

1. Reduce piles;
2. Heal piles;
3. Be effective in relieving severe or agonizing pain of piles;
4. Relieve all pain or itching caused by piles.

PAR. 7. In truth and in fact the use of DeWitt's Stainless Man Zan Pile Ointment, Man Zan Pile Ointment, DeWitt's Stainless Man Zan Suppositories, or each of them will not:

1. Reduce piles;
2. Heal piles;
3. Be effective in relieving severe or agonizing pain of piles;
4. Relieve all pain or itching caused by piles;
5. Afford any relief or have any therapeutic effect upon the condition known as piles, or upon any of the symptoms or manifestations thereof, in excess of affording temporary relief of minor pain or minor itching associated with piles.

Therefore, the advertisements referred to in Paragraph Five were and are misleading in material respect and constituted and now constitute, "false advertisements" as that term is defined in the Federal Trade Commission Act.

PAR. 8. The dissemination by the respondent of the false advertisements, as aforesaid, constituted, and now constitutes, unfair and deceptive acts and practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

OPINION OF THE COMMISSION

DECEMBER 16, 1966

BY JONES, *Commissioner*:

I

The complaint in this matter, issued on August 28, 1964, charged that respondent violated Sections 5 and 12 of the Federal Trade Commission Act by making false representations in advertising its preparations sold under the names of "DeWitt's Stainless Man Zan Pile Ointment," "Man Zan Pile Ointment," and "DeWitt's Stainless Man Zan Suppositories," for the treatment of hemorrhoids or piles.¹ The complaint alleged and respondent in its answer admitted that it maintained a course of trade in said preparation in commerce within the meaning of the Federal Trade Commission Act.

Paragraph Five of the complaint charged that the following were typical of the statements made by respondent in its advertising:

Itching and Soreness of hemorrhoid discomfort quickly relieved with DeWitt's Manzan. Manzan contains Allantoin for healing, benzocaine to ease pain, and a vasoconstrictor to help reduce swelling. For soothing action and fast palliative relief, try . . . Manzan ointment or Suppositories.

HEMORRHOIDS Real Relief . . . When simple hemorrhoids cause agony . . .

. . . a special healing agent.

. . . to ease pain . . . reduce swelling.

REAL RELIEF FROM HEMORRHOIDS

. . . now even more effective with Allantoin, a special healing agent.

Paragraph Six of the complaint charged that through the use of these advertisements and others respondent had represented that use of ManZan will: (1) reduce piles; (2) heal piles; (3) be effective in relieving severe or agonizing pain of piles; and (4) relieve all pain or itching caused by piles. Respondent denied the allegations in this paragraph except insofar as this paragraph alleged that respondent represented "that the use of its prepara-

¹ The terms "hemorrhoids" and "piles" are synonymous (Finding of Fact 11; and will be used interchangeably herein. Hereinafter the paragraphs of the Findings of Fact in this case will be referred to as "F.———."

tions will be effective in relieving pain of simple piles" (Answer, Par. 6).

In Paragraph Seven the representations set forth in Paragraph Six are alleged to be false and it is further alleged that ManZan will not "[a]fford any relief or have any therapeutic effect upon the condition known as piles, or upon any of the symptoms or manifestations thereof, in excess of affording temporary relief of minor pain or minor itching associated with piles." Therefore, it is concluded in this paragraph that respondent's advertisements were misleading in material respects and constituted "false advertisements" within the meaning of the Federal Trade Commission Act. Respondent denied the allegations in this paragraph except that it admitted that "the use of respondent's preparations will not relieve all pain or itching caused by piles" (Answer Par. 7).

The complaint in this matter was issued simultaneously with four other complaints also charging misrepresentations in the advertising of hemorrhoidal preparations, namely: *Humphreys Medicine Company, Incorporated*, Docket 8640 [p. 1502 herein], *American Home Products Corporation*, Docket 8641 [p. 1524 herein], *Grove Laboratories, Incorporated*, Docket 8643 [71 F.T.C. 822] and *The Mentholatum Company*, Docket 8644 [p. 1671 herein]. Hearings in the *American Home Products* case took place in April and May 1965, and the initial decision in that case was rendered on October 22, 1965. Complaint counsel appealed. On January 12, 1966, before argument of his appeal, complaint counsel moved in each of the other four cases to suspend hearings pending the issuance of the Commission's decision in *American Home Products*. This motion was denied by the Commission on March 16, 1966, and respondents in each of these four cases moved for reconsideration. On April 26, 1966 [69 F.T.C. 1179], the Commission entered an order directing the examiner to proceed with the hearings in each of these cases unless the parties desired to enter into a stipulation providing essentially that their cases may be disposed of on the basis of the record and findings in the *American Home Products* case. On May 25, 1966, respondent and complaint counsel filed a stipulation in accordance with the provisions of the Commission's order of April 26, 1966.² The stipulation provided that the Commission may issue such order as it deems necessary in the public interest on the basis of

² The terms of this stipulation (hereinafter referred to as "Stip.") are set forth in full in F.5.

the facts stipulated by the parties and that the respondent waived any intervening steps before the hearing examiner. The parties further stipulated that the advertisements in the case had no significantly different effect upon readers from the effect of the advertisements in *American Home Products*; that the effect of the use of respondent's preparation is not significantly different from the use of American Home Products' preparation; and that, to the extent that respondent's advertisements differ significantly from those in American Home Products, the Commission may, in its order disposing of this proceeding, include appropriate provisions to take into consideration such differences.

Attached to this stipulation are the texts of four virtually identical advertisements. The following is the full text of two of these advertisements:

Real Relief from Hemorrhoids. When simple hemorrhoids cause agony and embarrassing itch, use DeWitt's ManZan—now even more effective with Al-lantoin, a special healing agent. ManZan also contains benzocaine to ease pain, and a vasoconstrictor to help reduce swelling. For soothing action and fast palliative relief, try . . . ManZan—Ointment or Suppositories.

On the basis of the pleadings, the stipulation of the parties and the attached advertisements, together with such portions of the record in *American Home Products* as are specified in the attached findings, we conclude that we have jurisdiction over respondent and the subject matter and that respondent was engaged in commerce and accordingly are entering our Findings of Fact and Conclusions in the matter.

II

DISCUSSION OF ISSUES

A. *Representations Made by Respondent in Its Advertisements*

Respondent is charged with representing that its product will (1) reduce hemorrhoids, (2) heal hemorrhoids, (3) relieve all pain and be effective in relieving severe or agonizing pain of hemorrhoids, and (4) relieve all itching caused by hemorrhoids.

In *American Home Products* we found that respondent had represented that its preparation would "reduce or shrink hemorrhoids," "heal, cure, or remove hemorrhoids, and cause hemorrhoids to cease to be a problem," "relieve all pain attributed to or caused by hemorrhoids" and "eliminate all itch due to or ascribed to hemorrhoids" (F.8). In Par. 3 of the stipulation executed by the parties, it is provided that the advertisements in the instant case "had no significantly different effect upon readers from the effect

of the advertisements in *American Home Products*." Accordingly, on the basis of this provision of the parties' stipulation alone, we could conclude that respondent's advertisements represent that the alleged representations were in fact made by respondent. However, there is no need to rely exclusively on parties' stipulation for this conclusion since the advertisements speak for themselves and our own independent examination of them enables us to determine whether the complaint allegations as to the representations made in these advertisements may be sustained.

(1) Respondent's claims respecting shrinkage or reduction of hemorrhoids

Respondent's advertisements state that its products contain "a vasoconstrictor to help reduce swelling." Since a "vasoconstrictor" is an agent which causes constriction of blood vessels (Webster's New International Dictionary, Second Edition), the clear implication of this statement is that the hemorrhoids or blood vessels will be reduced and not merely that the overlying tissue will be reduced in size. Furthermore, the only meaning which the reader could ascribe to the claim that a medication for hemorrhoids will help reduce swelling is that it will reduce or shrink hemorrhoids. Accordingly, we conclude that respondent's claims in its advertising are tantamount to direct representations that its product will shrink hemorrhoids.

(2) Respondent's claims respecting healing of hemorrhoids

Respondent's advertisements state that ManZan contains "Al-lantoin, a special healing agent." Since the only apparent function of a "healing agent" would be to heal, the reference to such an agent necessarily carries with it the implication that respondent's product heals hemorrhoids. Thus, in our opinion respondent's claims are tantamount to representations that its product will heal hemorrhoids.

(3) Respondent's claims respecting pain

Respondent promises in its advertising that its product will provide "real relief from hemorrhoids" and states that ManZan, which "contains benzocaine to ease pain," should be used when "simple hemorrhoids cause agony." Respondent's claims are unequivocal and do not permit even an inference that the relief actually afforded may be partial or temporary. The reference to the word "benzocaine," a local anesthetic (Webster's New International Dictionary, Second Edition), implies that the preparation

will produce anesthesia or paralysis of the sensory apparatus in the affected area (Id.) thus effecting a total absence of pain or other feeling. In our opinion a substantial portion of the purchasing public would conclude from these broadly worded statements not merely that severe or agonizing pain will be relieved by ManZan, as alleged in Paragraph Six (3) of the complaint, but further that all pain resulting from hemorrhoids will be relieved, as alleged in Paragraph Six (4). Furthermore, the representations pertaining to healing referred to above would also tend to cause the reader to believe that the symptoms, including pain, would be eliminated after the "healing agent" had acted to heal the hemorrhoid. Accordingly, we conclude that the statements in respondent's advertisements constitute representations that its product will relieve all pain, including severe or agonizing pain, attributed to or caused by hemorrhoids.

(4) Respondent's claims respecting itching

Respondent advertises that its product should be used "when simple hemorrhoids cause agony and embarrassing itch," that "itching * * * of hemorrhoid discomfort [is] quickly relieved with DeWitt's ManZan" and the product offers "real relief from hemorrhoids." In our opinion these statements unquestionably promise complete relief from the itching due to hemorrhoids and that the average reader would be under the impression that if he used ManZan he would have real or entire relief from itching due to hemorrhoids.

B. *Deceptive Nature of Respondent's Claims*

The parties have stipulated that the facts applicable to this case support the stipulation that the effect of the use of respondent's preparation is not significantly different from the effect of American Home Products' preparations (Stip., Par. 4). Accordingly, the findings of fact and conclusions reached in *American Home Products* with respect to the efficacy of Preparation H, drawn from the record and Findings of Fact in that case, are equally applicable to ManZan. It is in the light of these findings and conclusions, therefore, that the allegations in Paragraph Seven must be analyzed. Respondent has admitted in its answer that ManZan "will not relieve all pain or itching" (Answer, Par. 7). Therefore, our discussion will be confined to the remaining issues relating to the efficacy of ManZan.

(1) Ability of ManZan to reduce hemorrhoids

Paragraph Seven (1) of the complaint alleges that, contrary to respondent's representations, ManZan will not reduce hemorrhoids.

Respondent advertises that ManZan contains "a vasoconstrictor to help reduce swelling." We have concluded that this representation amounts to a claim, and will be understood by the hemorrhoidal sufferer as a claim, that his hemorrhoids will be reduced in size. Hemorrhoids are by definition veins located underneath the mucous membrane of the rectum and the skin of the anal canal (F. 10). The evidence in the record is that hemorrhoidal preparations such as ManZan may have some effect upon edema or swelling in the tissue overlying hemorrhoids (F. 25(c), 26), but that they cannot reduce the size of the hemorrhoidal veins (F. 25(b), 26). The record also demonstrates, however, that this product can have no beneficial effect when the swelling is due to thrombosis (F. 25(c), 26). Thus, even if we were to assume that some reduction of swelling is effected by respondent's preparation, not all types of swelling will be affected in this way, and furthermore, the reduction which will occur will not be of the hemorrhoid itself but only of the surrounding area and thus will not be of the type implicitly promised by respondent's advertising. Accordingly, we find that respondent's representations with respect to reduction or shrinkage of hemorrhoids are in all respects false and misleading.

(2) Ability of ManZan to heal hemorrhoids

Paragraph Seven of the complaint alleges that contrary to respondent's representations, ManZan will not heal hemorrhoids. The record applicable to this case demonstrates that surgical removal is the only means by which hemorrhoids can be permanently cured (F. 22). Although certain symptoms may be ameliorated by other means (F. 24, 25) and may disappear spontaneously (F. 21), unless the underlying vascular condition is corrected, the patient will be subject to recurring episodes of symptoms (F. 21). Since ManZan cannot affect the underlying dilated veins it cannot heal or cure hemorrhoids (F. 25(a), 26).

(3) Ability of ManZan to relieve severe or agonizing pain caused by hemorrhoids

It is alleged in subparagraphs (2) and (3) of Paragraph 4 of the complaint that ManZan will not "relieve all pain * * * caused by piles or be "effective in relieving severe or agonizing pain of

piles." Respondent has admitted that its preparations "will not relieve all pain * * * caused by piles" (Answer, Par. 7). Since all pain is agonizing to many, if not most users and since ManZan admittedly cannot relieve all pain, it therefore follows that it is not capable of relieving "agonizing" pain in a substantial portion of hemorrhoidal sufferers. Furthermore, according to the record applicable to this case, severe pain in hemorrhoids is frequently caused by spasm or strangulation of a prolapsing internal hemorrhoid (F. 16) or by an external thrombotic hemorrhoid (F. 17) and that ManZan will have no effect upon pain when attributable to these causes (F. 25(d), 26). Thus it is clear that respondent's claims implying that it can eliminate all severe or agonizing pain of hemorrhoids are false and misleading.

C. Alleged Absence of Other Therapeutic Benefits of ManZan

In addition to the allegations that respondent's affirmative representations with respect to its product are false, the complaint also alleged that ManZan will not "[a]fford any relief or have any therapeutic effect upon any of the symptoms or manifestations thereof, in excess of affording temporary relief of minor pain or minor itching associated with piles" (Complaint, Paragraph Seven (5)).

As we have noted, the record demonstrates that surgical removal is the only means by which hemorrhoids can be permanently cured (F. 22) and that ManZan will not heal, cure or remove hemorrhoids or cause them to cease to be a problem (F. 25(a), 26). The record also demonstrates that while ManZan may in some cases provide some temporary relief from two symptoms of hemorrhoids, namely, pain and itching (F. 25(d) and (e), 26), it will not afford any other type of relief or have any other therapeutic effect upon hemorrhoids or its symptoms (F. 25 (e) (f), 26). Accordingly, we conclude that the allegations in Paragraph Seven (5) of the complaint must be sustained.

III

THE ORDER

The parties have stipulated that the Commission may issue such order as it deems necessary in the public interest, taking into consideration any significant differences between respondent's advertising and those of *American Home Products* (Stip., Pars. 6 and 7).

In determining what order is necessary to ensure that respondent's misrepresentations respecting the efficacy of its drug

preparation will not occur again, it is of primary importance to consider the segment of the public which is most likely to be particularly affected by these representations.

Our mandate under the law was graphically expressed by Judge Clark when he emphasized that "the law is not 'made for the protection of experts, but for the public—that vast multitude which includes the ignorant, the unthinking and the credulous.'" *Charles of the Ritz Distributing Corporation v. Federal Trade Commission*, 143 F. 2d 676, 679 (2nd Cir. 1944).

The need for protection of the public becomes particularly acute where misrepresentations are made with respect to health claims and the efficacy of drugs since the appeal of such representations falls most poignantly on those persons who are in distress, frequently the aged and the infirm. Moreover, today, with Medicare a reality, many people may be consulting doctors for the first time in their lives. They will be learning that aches and pains and discomforts of all kinds may be symptoms of diseases which they had never heard of before or never before associated with their own distress. Consequently, advertised claims of drug efficacy will have increasing relevance to this segment of our population and will offer hope of relief to millions in our population who may have previously ignored such advertising not realizing their possible application to their own conditions. Accordingly, it becomes of even greater importance today to make sure that representations respecting health claims and relief of distress are absolutely accurate and do not contain promises, impressions, or even highly veiled suggestions of efficacy which are in any sense false or misleading. It is with these basic principles in mind that we must fashion the type of prohibitive provisions which are necessary to be included in the order in this case.

A. *Product Application of the Order*

The order proposed by complaint counsel provided that it was to be applicable to ManZan "or any other preparation of *substantially similar composition or possessing substantially similar properties*" (emphasis added). As we noted in our opinion in *American Home Products* with respect to Preparation H, under such an order the respondent could easily replace the ingredients in its product with those that are not "substantially similar" or which did not possess "substantially similar properties" and be exempt from the order even though such substitute product may be equally ineffective in relieving symptoms of hemorrhoids

(*American Home Products* Opinion, pp. 1623-1625).³ And, as we further pointed out in *American Home Products*, determination of whether or not the new ingredients were "substantially similar" or possessed "substantially similar properties" "would be difficult of enforcement and would only be productive of controversy and probably litigation" (*American Home Products*, Opinion, p. 1623). Consequently, we are entering an order in the instant case, comparable to that entered in *American Home Products* which is applicable to all preparations which may be sold by respondent for relief or treatment of hemorrhoids or its symptoms regardless of whether they contain the same or different ingredients from those contained in ManZan. Finally, as we pointed out in detail in our opinion in the *American Home Products* case, this provision in no way hinders respondent from developing a truly efficacious remedy for hemorrhoids which might enable it to make some of the claims which this order now prohibits it from making. In this situation respondent need only apply to the Commission for a modification of the order as specifically provided for in the order which we are entering.

B. Respondent's Representations Respecting the Efficacy of ManZan

The order which we are entering prohibits respondent from representing directly or by implication that its product will reduce or shrink hemorrhoids; heal hemorrhoids; afford any relief from pain and itching, in excess of providing some temporary relief in some cases of pain and itching; or have any other effect on hemorrhoids or its symptoms. In connection with the prohibition of further representations as to ManZan's alleged ability to heal hemorrhoids we have also prohibited respondent from claiming that surgery may be avoided through the use of its product. Since surgery is the only certain cure for hemorrhoids (F. 22), it is obvious that the use of ManZan cannot obviate surgery where it is needed (F. 25(a), 26). Although respondent makes no specific claims to this effect in its present advertising, the Commission is obligated "to close all roads to the prohibited goal." *Federal Trade Commission v. Ruberoid*, 343 U.S. 470 (1953).

In its advertising respondent stresses that its preparations contain three ingredients: (1) "Allantoin, a special healing agent,"

³ It is apparent from the nature of the ingredients in respondent's preparation (F. 3) that they in all likelihood are replaceable by other ingredients which might have no different effect on hemorrhoids and yet be wholly outside the order if it applied only to ManZan or other preparations containing similar ingredients.

(2) "benzocaine to ease pain" and (3) "a vasoconstrictor to help reduce swelling." We are prohibiting respondent from referring to each of these ingredients.

(1) "*Allantoin*": Since, as we have found, ManZan cannot "heal" hemorrhoids, the so-called "healing agent," "*Allantoin*," can in fact perform no useful function. It is clear that continued reference by respondent to *Allantoin* in its advertising would be highly misleading and would imply to the public that the product is capable of healing hemorrhoids, whereas, according to the record, it is unable to provide more than some palliative relief. To prohibit respondent from representing that ManZan has any healing characteristics and to permit it to continue to represent that its product contains *Allantoin*, its purported "healing agent," would be to nullify in major part the prohibition respecting the curative properties of its product.

(2) "*Benzocaine*": As we have noted, the reference in respondent's advertising to "benzocaine," a local anesthetic, is equivalent to a direct claim that entire relief from pain in the affected area will be achieved. In view of our findings and conclusions that ManZan will not relieve all pain, any use of this term would therefore be wholly false and misleading. We have found that respondent's product will at best only afford some temporary relief in some cases of pain associated with some types of hemorrhoids. If this temporary relief is due to benzocaine, it would be redundant to permit respondent to single this ingredient out for special mention in its advertisement in addition to making the permitted disclosure respecting temporary relief for some cases of pain and would serve only to confuse and mislead the reader or hearer. To the extent singling such an ingredient out for special emphasis conveyed an impression different from this disclosure, it would be false and misleading. Accordingly, we have prohibited use of this word.

(3) "*Vasoconstrictor*": As we have pointed out, ManZan is not capable of reducing the size of hemorrhoids. Since, as we have further found, the word "vasoconstrictor" (literally [blood] vessel constrictor) implies that the hemorrhoid will be shrunk, the further reference by respondent to this ingredient can only have the effect of emphasizing that which ManZan is incapable of achieving: the shrinkage of hemorrhoids. To avoid the deception inherent in the use of this word we have ordered that respondent discontinue its use.

Finally, in view of the likelihood that reference to any single

ingredient may convey the impression that such ingredient is of special importance in the treatment or relief of hemorrhoids, we have provided that respondent may not refer to any other ingredient either singly or in combination unless each such ingredient is effective in the treatment or relief of hemorrhoids or any of its symptoms and unless the specific effect thereof is expressly and truthfully set forth.

FINDINGS OF FACT, CONCLUSIONS AND ORDER

FINDINGS OF FACT

A. Respondent and its Products

1. Respondent E. C. DeWitt & Co., Inc., is a corporation, organized, existing and doing business under the laws of the State of New York, with its principal office and place of business located at 730 Fifth Avenue, in the city of New York, State of New York (Complaint, Par. 1; Answer, Par. 1).

2. Respondent E. C. DeWitt & Co., Inc., is now and has been for more than one year last past, engaged in the sale and distribution of three preparations coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act (Complaint, Par. 2; Answer, Par. 2).

3. The designations used by respondent E. C. DeWitt & Co., Inc., for said preparations, the formulas thereof and the directions for use are as follows:

A. Designation: "DeWitt's Stainless Man Zan Pile Ointment."

Formula: Active Ingredients: CARBOLIC ACID $\frac{1}{2}\%$ BENZOCAINE, ZINC OXIDE, ALLANTOIN, EPHEDRINE HCl.

Directions: For palliative relief cleanse affected parts with warm water and toilet soap; dry with soft towel. After gently inserting the Stainless Man Zan applicator as far as possible into the rectum, squeeze tube to apply a liberal quantity. Use night and morning, also after stooling when convenient.

CAUTION: Avoid using this preparation in case of undue bleeding, since this may indicate a serious condition requiring medical advice.

B. Designation: "Man Zan Pile Ointment."

Formula: Active ingredients: Ephedrine HCl Allantoin, Benzocaine Carbolic Acid 0.5% Menthol, Tannic Acid.

Directions: For palliative relief cleanse affected parts with warm water and toilet soap; dry with soft towel. After gently inserting the Man Zan applicator as far as possible into the rectum, squeeze tube to apply a liberal quantity. Use night and morning, also after stooling when convenient.

CAUTION: Avoid using this preparation in case of undue bleeding since this may indicate a condition requiring medical advice.

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C. Designation: "DeWitt's Stainless Man Zan Suppositories."

Formula: Active Ingredients: Benzocaine Zinc Oxide, Phenol 0.5% Allantoin, Phenylpropanolamine.

Directions: Before using Man Zan Suppositories remove the protective foil wrapping. Wash affected parts, then insert the suppository as high as possible into the rectum. Use morning and night and after each bowel movement. Treatment should be continued daily for best results. External discomforts are best treated with Man Zan Pile Ointment—Stainless or Regular.

CAUTION: If relief is not obtained in a reasonable period of time, and in cases of undue bleeding, consult your physician.

4. Respondent E. C. DeWitt & Co., Inc., causes the said preparations, when sold, to be transported from its place of business located at 2835 Sheffield Avenue, Chicago 14, Illinois, to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act (Complaint, Par. 3; Answer, Par. 3).

B. Stipulation Entered Into By Parties Hereto

5. The parties hereto entered into a Stipulation, filed on May 25, 1966, providing as follows:

1. This proceeding may and shall be submitted to the Commission for disposition on the basis of record in Docket 8641, *American Home Products Corporation*, and such other stipulations and records as are provided for herein.

2. The advertisements attached to and made a part of this stipulation are representative of respondent's advertising claims for its product ManZan and are to be included in the record of these proceedings.

3. The advertisements in this case had no significantly different effect upon readers from the effect of the advertisements in *American Home Products* and the facts applicable to this case support this stipulation.

4. The effect of the use of respondent's preparation, Man Zan, is not significantly different from the use of American Home Products preparation, known as "Preparation H," and the facts applicable to this case support this stipulation.

5. The respondent waives any further intervening procedural steps before the Hearing Examiner.

6. The Commission may, on the basis of this stipulation, the attached advertisements and the record in *American Home Products*, issue such order as it deems necessary to the public interest.

7. To the extent that the respondent's advertisements differ significantly to those in *American Home Products*, the Commission may, in its order disposing of the proceedings, include appropriate provisions to take into consideration such differences.

8. The Commission is to issue its order disposing of these proceedings con-

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currently with the order setting forth its final decision in *American Home Products*.

9. The record on which the Commission is to make its disposition of the proceeding and for the purposes of judicial review, is limited to the record at the time this stipulation is filed, this stipulation with the attached advertisements and the record in *American Home Products*.

Attached to this stipulation (hereinafter referred to as "Stip.") are copies of four of respondent's advertisements.

C. Representations Made

6. In the course and conduct of its said business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning the said preparation in commerce, as "commerce" is defined in the Federal Trade Commission Act, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparation; and has disseminated, and caused the dissemination of, advertisements concerning said preparation for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparation in commerce, as "commerce" is defined in the Federal Trade Commission Act (Complaint, Par. 4; Answer, Par. 4; Stip., Par. 2).

7. Among the statements and representations contained in said advertisements disseminated as hereinabove set forth are the following:

Real relief from Hemorrhoids. When simple hemorrhoids cause agony and embarrassing itch, use DeWitt's ManZan—now even more effective with Allantoin, a special healing agent. ManZan also contains benzocaine to ease pain, and a vasoconstrictor to help reduce swelling. For soothing action and fast palliative relief, try . . . MANZAN Ointment or suppositories.

Itching and soreness of hemorrhoid discomfort quickly relieved with DeWitt's ManZan. ManZan contains Allantoin for healing, benzocaine to ease pain, and a vasoconstrictor to help reduce swelling. For soothing action and fast palliative relief, try . . . MANZAN Ointment or Suppositories.

(Stip.[attachments]).

D. Meaning of Respondent's Representations

8. In *American Home Products Corporation*, Docket 8641 [p. 1524 herein], we found that through the use of American Home Products Corporation's advertisements, said respondent has represented and is now representing, directly and by implication, that the use of Preparation H Ointment and Suppositories, and each of them, will:

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- (a) Reduce or shrink hemorrhoids;¹
- (b) Avoid the need for surgery as a treatment for hemorrhoids;
- (c) Eliminate all itch due to or ascribed to hemorrhoids;
- (d) Relieve all pain attributed to or caused by hemorrhoids;
- (e) Heal, cure or remove hemorrhoids, and cause hemorrhoids to cease to be a problem.

(*American Home Products Corporation*, Docket 8641, Finding of Fact 7.²)

9. Through the use of the advertisements set forth in paragraph 7 hereof, and others similar thereto not specifically set out therein, respondent has represented and is now representing, directly and by implication, that the use of ManZan Ointment or Suppositories will:

- (a) Reduce or shrink hemorrhoids;
- (b) Avoid the need for surgery as a treatment for hemorrhoids;
- (c) Eliminate all itch due to or ascribed to hemorrhoids;
- (d) Relieve all pain attributed to or caused by hemorrhoids;
- (e) Heal, cure or remove hemorrhoids, and cause hemorrhoids to cease to be a problem.

(Stip., Par. 3.)

E. *General Medical Facts Pertaining to Hemorrhoids and Their Treatment*

10. "Hemorrhoids" are masses of dilated weak-walled veins located underneath the mucous membrane of the lower portions of the rectum and under the skin of the anal canal and the peri-anal area (A.H.P. Tr. 193, 255, 340, 413-414, 478, 543, 606, 709, 817, 838, 867, 892).³

11. The terms "hemorrhoids" and "piles" are synonymous (A.H.P. Tr. 117, 193, 255, 340, 414, 478-479, 543, 607 and 709).

12. "Internal hemorrhoids" are hemorrhoids occurring above the pectinate line and are covered by mucosa. "External hemorrhoids" are hemorrhoids occurring below the pectinate line and are covered by skin (A.H.P. Tr. 193, 199, 232, 236, 255-257, 262, 342, 420, 421, 486, 548, 549, 608, 609, 817, 838, 867 and 892).

13. An "external thrombotic hemorrhoid" is a blood clot under

¹ The words "hemorrhoids" and "piles" are synonymous (See Finding 11, *infra*) and will be used interchangeably herein.

² The paragraphs of the Findings of Fact in *American Home Products* are hereinafter referred to as "A.H.P. —."

³ The references are to the transcript in *American Home Products*.

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the surface of the skin located in the immediate vicinity of the anal opening (A.H.P. Tr. 117). It is also referred to as an "anal hematoma" (A.H.P. Tr. 719) or a "perianal thrombosis" (A.H.P. Tr. 549).

14. A "prolapse" or "prolapsing hemorrhoid" is an internal hemorrhoid which, due to laxity of the rectum is enabled to fall outside the anal canal and protrudes to the surface (A.H.P. Tr. 199).

15. Hemorrhoids develop in a human being largely because of the fact that he stands in an upright position. In such a position a column of blood is formed from the splenic to the superior hemorrhoidal vein. The hemorrhoidal veins do not have valves to support the weight of this column of blood. The resulting pressure causes the hemorrhoidal veins to dilate (A.H.P. Tr. 594, 231). Hemorrhoids tend to be hereditary (A.H.P. Tr. 144, 231). Other factors leading to the development of hemorrhoids are abnormally long periods of standing, straining, difficulty with bowel movement, impacted stool, pregnancy and cirrhosis of the liver (A.H.P. Tr. 231-232, 144).

16. The most common symptom of internal hemorrhoids is bleeding (A.H.P. Tr. 256, 393 479). The other principal symptom of internal hemorrhoids is prolapse (A.H.P. Tr. 256). Pain rarely occurs in internal hemorrhoids since the sympathetic nervous system which services the region above the pectinate line where hemorrhoids are located does not contain sensory nerve fibers (A.H.P. 266, 294, 342-343). Pain, however, may occur in infrequent cases of severe complicated internal hemorrhoids as the result of spasm or strangulation caused by prolapse or as the result of the involvement of tissues beyond the pectinate line (A.H.P. Tr. 342, 415, 631-632, 723).

17. The most common symptoms of external hemorrhoids are pain and swelling (A.H.P. Tr. 256, 742). Pain in external hemorrhoids is frequently caused by an external thrombotic hemorrhoid (A.H.P. Tr. 503). Other causes of pain in external hemorrhoids are inflammation, swelling and ulceration (A.H.P. Tr. 174, 267, 358, 519). Pain may also result from infection. However, this cause of pain is a relatively infrequent occurrence since the rectal and anal area is relatively highly resistant to infection (A.H.P. Tr. 520) and thus infection occurs very rarely as a symptom of hemorrhoids (A.H.P. Tr. 315).

18. Swelling, as distinguished from the dilation of the hemorrhoidal veins, may be a symptom of hemorrhoids as well as a

possible cause of pain in external hemorrhoids. Swelling usually results either from a blood clot or thrombosis, which causes distension in the tissue overlying the hemorrhoid, or from edema, which is the accumulation of serous fluid in the interfibrillar spaces in such tissue (A.H.P. Tr. 144, 550).

19. Itching is not a common symptom of internal or external hemorrhoids (A.H.P. Tr. 129, 265, 618-619, 727). The itching thought to be caused by hemorrhoids is usually the result of some other condition such as fungus infection or idiopathic pruritis (A.H.P. Tr. 326, 502, 504, 347, 618-619, 727). The itching which is caused by hemorrhoids is usually the result of discharge from a prolapsed internal hemorrhoid (A.H.P. Tr. 318, 425, 618-619), or healing of an external hemorrhoid (A.H.P. Tr. 265, 502).

20. The symptoms of hemorrhoids can be confused with other conditions such as fissure, fistula, peri-anal or peri-rectal abscess, hypertrophic papillae, papillitis, cryptitis, polyps, proctitis, ulcerative colitis, pruritis ani and carcinoma (cancer). Any of these conditions can co-exist with hemorrhoids and it is not uncommon to find such a situation (A.H.P. Tr. 114-115, 196-197, 205, 259-260, 347-349, 483-484, 545-546, 612-613, 714-715).

21. The symptoms of hemorrhoids often disappear spontaneously within short periods of time, which may range from several days to two weeks (A.H.P. Tr. 119, 264, 324, 355, 361, 424, 875, 1613). However, the underlying pathology, namely, the vascular dilation, will persist unless corrected and will be subject to recurring episodes of symptoms (A.H.P. Tr. 516, 214).

22. Surgical removal is the only means by which hemorrhoids can be permanently cured (A.H.P. Tr. 118-119, 195, 200-202, 262-263, 352, 422, 487, 550, 554, 623, 719-723, 830). However, surgery does not effect a complete cure in every case (A.H.P. Tr. 150). Surgery may not be advisable or necessary in every case. Surgery may be contra-indicated in cases in which the patient's general medical condition is such that the danger of anesthesia and surgery outweigh the possible benefits to be derived (A.H.P. Tr. 226). Surgery is also not advisable for a simple, uncomplicated hemorrhoid (A.H.P. Tr. 169). Although hemorrhoids may be uncomfortable they are rarely a very serious medical problem, so that a patient, if he chooses to avoid surgery or should avoid it for medical reasons, can go through life without having his hemorrhoids removed (A.H.P. Tr. 135).

23. The symptoms of simple, uncomplicated, internal hemorrhoids of small size can frequently be ameliorated by injectional

therapy. This consists of the injection of a sclerosing solution into the hemorrhoid itself which causes scar tissue to form which cuts off the blood vessel feeding the hemorrhoid (A.H.P. Tr. 145, 200, 262-263, 353). A further treatment which has been used within the last several years is the baron ligation method whereby a ligature of rubber is placed around internal hemorrhoids as another means of cutting off blood circulation to the hemorrhoid (A.H.P. Tr. 200-201, 488).

24. In cases on which surgery, injectional therapy or the baron ligation method are not used, a so-called "conservative" course of treatment may be prescribed. The measures used in such a course of treatment include cleanliness, altering of the diet to eliminate irritative foodstuffs, control of the bowels to ensure a smooth, soft stool, warm baths, witch hazel, boric acid, local anesthetic, ointments, suppositories, avoidance of standing and manual reinsertion of prolapse (A.H.P. Tr. 120, 202, 306, 356-357, 684-686). Ointments and suppositories contain lubricants which may protect the anal and rectal canal against the passage of hard, dry stool. Such lubricants may also serve to relieve dryness and soften the skin as well as provide a psychological advantage; many people derive mental relief from the fact that some sort of treatment is applied (A.H.P. Tr. 203-204, 279, 313, 355, 358, 362-363, 525, 555, 557).

F. Conclusions re Effect of ManZan Ointment and Suppositories

25. In *American Home Products* we reached the following conclusions with respect to the effect of Preparation H Ointment and Suppositories on hemorrhoids and its symptoms based on citations set forth below:

(a) Preparation H will not avoid the need for surgery where it is indicated, or heal, cure or remove hemorrhoids, or cause hemorrhoids to cease to be a problem (A.H.P. 25, 26, 28, 29; A.H.P. Initial Decision, p. 1602; conceded by respondent on appeal (A.H.P. 31)).

(b) Preparation H cannot reduce the size of hemorrhoidal veins (A.H.P. Tr. 128-129, 173-174, 212-213, 276, 369-370, 436-437, 500, 563-564, 629-630, 740, 1497, 1668) (A.H.P. 32).

(c) Preparation H may possibly, through the lubricants which it contains, temporarily protect inflamed surface areas from the passage of hard, dry stool and thereby have some effect upon edema or swelling in the tissue overlying hemorrhoids (A.H.P. Tr. 202, 1471, 1570, 1668. But cf. Tr. 128-129, 463, 684, 742-743).

However, where swelling is due to thrombosis (A.H.P. Tr. 264), it will have no beneficial effect (A.H.P. Tr. 503, (A.H.P. 33).

(d) Preparation H may in some cases afford some temporary relief against some types of pain associated with hemorrhoids (A.H.P. Tr. 131, 207, 279, 372-373, 439-440, 503, 566, 632-633, 744). Through the lubricants which it contains, this medication may protect inflamed surface areas against the passage of hard, dry stool and thereby temporarily relieve some pain caused by ulceration or from edema or swelling resulting from such inflammation (A.H.P. Tr. 174, 212-213, 358, 493, 525, But *cf.* Tr. 128-129, 463, 684, 742-743). Preparation H can, however, have no effect upon pain due to thrombosis (A.H.P. Tr. 295, 358, 503) or due to spasm or strangulation caused by prolapsing internal hemorrhoids (A.H.P. Tr. 631-632) (A.H.P. 34).

(e) Through the lubricants which it contains, Preparation H may possibly relieve dryness and surface irritation and thereby provide some temporary relief from some types of itching associated with hemorrhoids (A.H.P. Tr. 131, 215, 279-280, 373-374, 439-440, 503-504, 566, 633-634, 741) (A.H.P. 35).

(f) Except for the effects set forth in A.H.P. 33, 34, 35, as well as possible psychological effects (see A.H.P. 28), Preparation H will not have any beneficial effect in the treatment or relief of hemorrhoids or any of its symptoms (A.H.P. Tr. 131, 215, 279, 315-316, 372-373, 424, 439-440, 503-504, 566, 632-633, 682-683, 744; Answer, Par. 3) (A.H.P. 36).

26. We hereby enter findings with respect to the effect of ManZan Ointment and Suppositories on hemorrhoids and its symptoms and manifestations identical to the findings with respect to Preparation H set forth in paragraph 25 hereof (Stip., Par. 4; Answer, Par. 7).

CONCLUSIONS RE ALLEGATIONS IN COMPLAINT

1. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of respondent.

2. Through the use of the advertisements set forth in paragraph 7 hereof and other similar thereto not specifically set out therein, respondent has represented and is now representing, directly and by implication, that the use of ManZan Ointment and Suppositories, will:

- (a) Reduce hemorrhoids;
- (b) Relieve all itch and all pain, including severe or agonizing pain, associated with hemorrhoids;

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(c) Heal hemorrhoids;

3. ManZan Ointment and Suppositories will not:

(a) Reduce hemorrhoids;

(b) Heal hemorrhoids;

(c) Eliminate all itch or pain or all severe or agonizing pain, due to or ascribed to hemorrhoids or afford any relief from pain or itching associated with hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids; or

(d) Afford any other type of relief or have any other therapeutic effect upon hemorrhoids or upon any of the symptoms or manifestations thereof.

4. Therefore, the advertisements referred to in paragraph 7 hereof were and are misleading in material respects and constituted and now constitute "false advertisements" as that term is defined in the Federal Trade Commission Act; and the dissemination of said false advertisements constituted, and now constitutes, unfair and deceptive practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

ORDER

I. *It is ordered*, That respondent E. C. DeWitt & Co., Inc., a corporation, and its officers, representatives, agents and employees, directly or through any corporate or other device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act:

A. In connection with the offering for sale, sale or distribution of DeWitt's Stainless ManZan Pile Ointment, ManZan Pile Ointment, DeWitt's Stainless ManZan Suppositories, or any other product offered for sale for the treatment or relief of hemorrhoids or piles or any of its symptoms which:

1. Represents directly or by implication that the use of such product will:

(a) Reduce or shrink hemorrhoids or hemorrhoidal tissue or membranes or reduce or shrink swelling associated with hemorrhoids;

(b) Avoid the need for surgery as a treatment for hemorrhoids or hemorrhoidal symptoms;

(c) Heal or cure hemorrhoids;

(d) Relieve agonizing or severe pain of hemor-

rhoids or afford any relief from pain or itching attributed to or caused by hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids;

(e) Afford any other type of relief or have any other therapeutic effect upon the condition known as hemorrhoids or upon any of the symptoms or manifestations thereof.

2. Contains any reference (a) to the word "Allantoin"; (b) to the word "benzocaine" or to any word such as "anesthetic" which implies that said product will provide relief from pain or itching associated with hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids; or (c) to any word such as "vasoconstrictor" which implies that said product will shrink hemorrhoids.

3. Contains any reference to any other ingredient either singly or in combination unless each such ingredient is effective in the treatment or relief of hemorrhoids or any of its symptoms and unless the specific effect thereof is expressly and truthfully set forth.

B. Disseminating, or causing to be disseminated, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of respondent's preparation or preparations, in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraph I(A) hereof.

II. In the event that respondent at any time in the future markets any preparation for the treatment or relief of hemorrhoids or any of its symptoms for which it desires to make any of the representations now prohibited under Paragraph I(A) of this order, it may petition the Commission for a modification of the order. Such petition shall be accompanied by a showing that the representation is not false or misleading within the meaning of the Federal Trade Commission Act, and, if such has been the case, that the specific representation has been approved by the Secretary of the Department of Health, Education and Welfare under the provisions of the Federal Food, Drug and Cosmetic Act as it is presently constituted or as it may hereafter be amended.

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It is further ordered, That respondent shall, within sixty (60) days after service upon it of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order to cease and desist.

FINAL ORDER

The parties having entered into a stipulation filed on May 25, 1966, providing, *inter alia*, that: the case would be submitted to the Commission on the record in Docket 8641, *American Home Products Corporation* [p. 1524 herein], and such other facts and records as provided for in said stipulation; that the advertisements in the case had no significantly different effect upon readers from the effect of the advertisements in *American Home Products*; that the effect of the use of respondent's preparation is not significantly different from the use of American Home Products' preparation; that to the extent that respondent's advertisements differ significantly from those in *American Home Products*, the Commission may, in its order disposing of this proceeding, include appropriate provisions to take into consideration such differences; that respondent waives any further intervening steps before the hearing examiner; that the Commission may, on the basis of this stipulation, the advertisements attached thereto and the record in *American Home Products*, issue such order as it deems necessary to the public interest and that the record on which the Commission is to make its disposition of this proceeding is limited to the record at the time this stipulation is filed; and the Commission having rendered its decision and issued its Opinion herein;

Now therefore, on the basis of said stipulation and attachments, the pleadings herein and the record in Docket 8641, *American Home Products Corporation* [p. 1524 herein], it is hereby

Ordered, That the attached Findings of Fact, Conclusions and Order be and they hereby are entered and issued by the Commission in final disposition of this proceeding.

Complaint

IN THE MATTER OF

THE MENTHOLATUM COMPANY

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE
FEDERAL TRADE COMMISSION ACT

*Docket 8644. Complaint, Aug. 28, 1964—Decision, Dec. 16, 1966**

Order requiring a Buffalo, N.Y., manufacturer of "Mentholum M.P.O." pile ointment to cease falsely representing in its advertising that its product will shrink, avoid need for surgical treatment on, heal, cure, or remove hemorrhoids or effect any other cure beyond temporary relief.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that The Mentholum Company hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent The Mentholum Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 1360 Niagara Street in the city of Buffalo, State of New York.

PAR. 2. Respondent The Metholatum Company is now, and for some time last past has been, engaged in the sale and distribution of a preparation offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act.

The designation used by respondent The Mentholum Company for said preparation, the formula thereof and directions for use are as follows:

Designation: "Mentholum M.P.O." *Medicated* Pile Ointment.

Formula: The active ingredients for "Mentholum M.P.O." *Medicated* Pile Ointment are as follows:

Benzocaine; Hexachlorophene; Ephedrine sulfate, lanolin, in an exclusive prescription-type base that is temperature-stable.

Directions: Apply freely night and morning and after each bowel movement. Use scientific applicator for internal hemorrhoids. Lubricate before use

*Modified on Dec. 15, 1970.