

Complaint

103 F.T.C.

IN THE MATTER OF

ADRIA LABORATORIES, INC.

CONSENT ORDER IN REGARD TO ALLEGED VIOLATION OF SECS. 5 AND 12
OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3135. Complaint, June 5, 1984—Decision, June 5, 1984*

This consent order requires a Dublin, Ohio manufacturer and seller of over-the-counter drugs, among other things, to cease promoting "Efficin," or any other over-the-counter internal analgesic containing magnesium salicylate, by representing that the product contains no aspirin, or by comparing the product's safety to any product containing aspirin, unless representations are accompanied by prescribed disclosure warnings and substantiated by reliable and competent scientific evidence.

Appearances

For the Commission: *T. Bringier McConnell*, Washington, D.C.

For the respondent: *Alan A. Kaplan, Kleinfeld, Kaplan & Becker*, Washington, D.C., and *Bethany A. Beck*, in-house counsel, Columbus, Ohio.

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 Adria Laboratories, 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 is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located in Dublin, Ohio.

PAR. 2. Respondent is now and for some time in the past has been engaged in the manufacture, offering for sale, and sale of over-the-counter drugs, including Efficin.

PAR. 3. Respondent has caused to be prepared and placed for publication and has caused the dissemination of advertising and promo-

tional material, including, but not limited to, the advertising and labeling referred to herein, to promote the sale of Efficin.

PAR. 4. Respondent operates in various States of the United States and in the District of Columbia. Respondent's manufacture, offering for sale, sale, and distribution of over-the-counter drugs, including Efficin, mentioned herein, constitutes maintenance of a substantial course of trade in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. In the course and conduct of its business, and at all times mentioned herein, respondent has been, and is now, in substantial competition in or affecting commerce with firms and corporations engaged in the sale of merchandise of the same general kind and nature as merchandise sold by respondent.

PAR. 6. In the course and conduct of its business, respondent has disseminated and caused the dissemination of advertisements for over-the-counter drugs, including Efficin, by various means in or affecting commerce, including, *inter alia*, broadcast, national magazines, product labels, point-of-sales brochures, and other means, distributed by mail and across state lines, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said products.

PAR. 7. Typical advertisements and promotional materials, disseminated as previously described, are attached hereto as Exhibits A through I. Included *inter alia* in those advertisements and promotional materials is the statement "Contains No Aspirin. . . ."

PAR. 8. Through the use, *inter alia*, of the advertisements referred to in Paragraph Seven, and other advertisements or promotional materials not specifically set forth herein, respondent has represented, and now represents, to consumers directly or by implication, one or more of the following:

(a) Efficin is not associated with most of the side effects and contraindications with which aspirin is associated.

(b) Use of Efficin poses a lesser risk of suffering the side effects associated with aspirin than does use of aspirin.

(c) The side effects associated with both aspirin and Efficin are less severe with Efficin than with aspirin.

PAR. 9. The representation in Paragraph Eight (a) is false, for the reason that Efficin is similar to aspirin, and that the ingredient in Efficin has been associated with most of the same side effects and contraindications as aspirin.

PAR. 10. Through the use of the advertisements referred to in Paragraph Seven, and other advertisements not specifically set forth herein, respondent has represented, directly or by implication, that it

possessed and relied upon a reasonable basis for the representations set forth in Paragraph Eight (b) and (c) at the time of the initial dissemination of the representations and each subsequent dissemination. In truth and in fact, respondent did not possess and rely upon a reasonable basis for making such representations. Therefore, respondent's making and dissemination of said representations, as alleged, constituted and now constitute unfair and deceptive acts or practices.

PAR. 11. Respondent has failed to disclose in the advertisements referred to in Paragraph Seven that Efficin is similar to aspirin, and that the ingredient in Efficin has been associated with many of the same side effects and contraindications as aspirin. In light of the statements and representations referred to in Paragraph Eight, such failure is an omission of material fact, and the advertisements referred to above are false within the meaning of Section 12 of the Federal Trade Commission Act.

PAR. 12. The use by respondent of the aforesaid statements, representations, acts, and practices, directly or by implication, and the placement in the hands of others of the means and instrumentalities by and through which others may have used the aforesaid statements, representations, acts, and practices, have had and now have the capacity and tendency to mislead consumers into the erroneous and mistaken belief that said statements and representations were and are true and complete and to induce such persons to purchase Efficin by reason of said erroneous and mistaken belief.

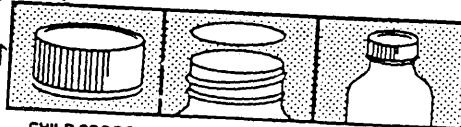
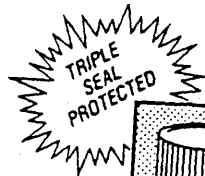
PAR. 13. The aforesaid acts or practices of respondent, herein alleged as deceptive, were and are all to the prejudice and injury of the public and constituted and now constitute unfair or deceptive acts and practices in or affecting commerce and false advertisements in violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended.

EXHIBIT A

INTRODUCING
efficin[®]
 TABLETS



A pain reliever
 that's safe
 in more ways
 than one.



CHILD PROOF
 TWIST OFF CAP

BOTTLE TOP SEAL

CLEAR PLASTIC,
 TAMPER RESISTANT,
 SHRINK WRAP

- SAFE PACKAGING
- CONTAINS NO ASPIRIN
 OR ACETAMINOPHEN
- RECOMMENDED & PRESCRIBED
 BY PHYSICIANS FOR MANY YEARS
- FEWER TABLETS NEEDED
 BECAUSE OF THE EXTRA STRENGTH

Complaint

EXHIBIT B

CO-OP AD

Introducing
Extra Strength
efficin
TABLETS



\$0.00

- Triple Seal Protected
- Child proof twist off cap
- Bottle Top Seal
- Clear plastic, tamper resistant, shrink wrap

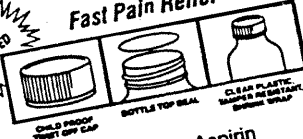
FAST PAIN RELIEF
EXTRA STRENGTH
efficin
TABLETS

- contains no aspirin
- clinically proven effective

\$0.00

efficin
TABLETS

Fast Pain Relief



- Contains No Aspirin or Acetaminophen
- Recommended and prescribed by Physicians for many years
- Fewer tablets needed because of the extra strength

Introducing
EXTRA STRENGTH
efficin
TABLETS



\$0.00



- Contains No Aspirin or Acetaminophen
- Recommended and prescribed by Physicians for many years
- Fewer tablets needed because of the extra strength

EXHIBIT C

INTRODUCING

efficin[®]

TABLETS



A pain reliever
that's safe
in more ways
than one.

EXTRA STRENGTH
efficin
TABLETS
FAST PAIN RELIEF

CONTENTS 500 MG Magnesium Salicylate 36 ANALGESIC TABLETS

TRIPLE SEAL PROTECTED



CHILD PROOF
TWIST OFF CAP



BOTTLE TOP SEAL



CLEAR PLASTIC,
TAMPER RESISTANT,
SHRINK WRAP

- SAFE PACKAGING
- CONTAINS NO ASPIRIN
OR ACETAMINOPHEN
- RECOMMENDED & PRESCRIBED
BY PHYSICIANS FOR MANY YEARS
- FEWER TABLETS NEEDED
BECAUSE OF THE EXTRA STRENGTH

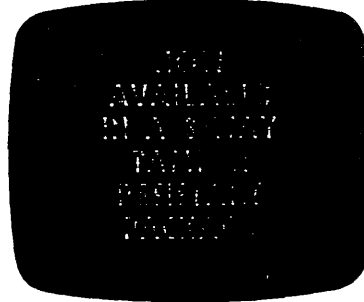
EXHIBIT D

Introducing extra strength **efficin**

EFFICIN :30 SEC. TV



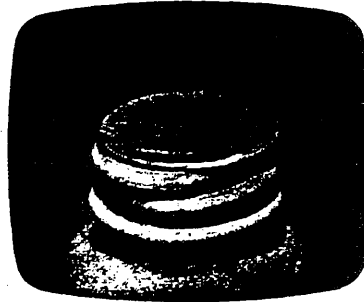
VO: ANNOUNCER
Introducing extra strength efficin tablets. Fast pain relief that contains no aspirin or acetaminophen.



VO: ANNOUNCER
Efficin's active ingredient has been recommended by physicians for years and now it's available in a three way tamper resistant package.



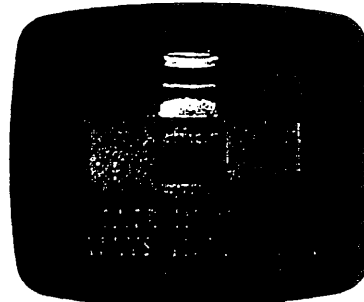
VO: ANNOUNCER
Efficin's bottle is safely sealed in clear plastic wrap.



VO: ANNOUNCER
There's a safety seal under the cap.



VO: ANNOUNCER
The cap is child resistant.



VO: ANNOUNCER
Efficin...
Extra strength pain relief. Safe in more ways than one.

EXHIBIT E

Radio TV Reports

41 East 42nd Street New York N.Y. 10017
(212) 599-5500

PRODUCT
PROGRAM

EXTRA STRENGTH EFFICIN TABLETS
THE NEW \$25,000 PYRAMID 11/23/82
WISH-TV (INDIANAPOLIS) 30 SEC
10:07AM



1. ANNCR: Introducing Extra Strength Efficin Tablets.



2. Fast pain relief that contains no aspirin or acidomeniphen.



3. Efficin's active ingredient has been recommended by physicians for years.



4. and now it's available in a 3-way tamper resistant package.



5. Efficin's Bottle is safety sealed in clear plastic wrap.



6. There's a safety seal under the cap.



7. The cap is child resistant.



8. Efficin.



9. Extra strength pain relief.

ALSO AVAILABLE IN COLOR VIDEO-TAPE CASSETTE

While Radio TV Reports Inc. endeavors to assure the accuracy of material supplied by it, it cannot be responsible for mistakes or omissions.

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EXHIBIT F

Introducing

EXTRA STRENGTH **efficin**[®]
Magnesium Salicylate
PAIN RELIEF TABLETS



SAFE IN MORE WAYS THAN ONE!

Relief for the discomfort of headaches, aches, pains, neuralgia and for temporary relief of minor pain due to arthritis and rheumatism.

TRIPLE
SEAL
PROTECTED

- Safe Packaging
- The Ingredient in **efficin**[®] has been Recommended by Physicians and Pharmacists for many years
- Fewer Tablets Needed Because of the Extra Strength

ON YOUR NEXT PURCHASE OF
EXTRA STRENGTH **efficin**[®]
PAIN RELIEVER TABLETS

SAVE 50¢



Present this coupon when you buy the 36 tablet bottle and your druggist or grocer will deduct 50¢ from the regular purchase price, subject to the terms below.

RETAILER: You are authorized to act as our agent for redemption of this coupon. We will pay you the face value plus 5¢ handling provided you and the consumer have complied with the terms of the offer.

OFFER TERMS: This coupon is good only when redeemed by you from a consumer at time of purchasing specified brand. Any sales tax must be paid by consumer. Invalids showing your purchase of sufficient stock to cover all coupons redeemed must be shown on request. Void if used, restricted or prohibited by law or if presented by any outside agencies, brokers, industrial or institutional users. Cash value: 1/20 of 1¢.

Send Coupon to: Warner-Lect Laboratories, Inc., P.O. Box 2450, Columbus, Ohio 43224.

Offer limited to one coupon per specified product and size. Expires 6/30/84. This coupon good at your dealer's for one 36 tablet bottle of Extra Strength efficin Pain Reliever Tablets.

Printed in USA

EXHIBIT G

Introducing

EXTRA
STRENGTH

efficin[®]

PAIN RELIEF TABLETS

Safe in More Ways Than One!



- Safe Packaging
- Contains Magnesium Salicylate
- The Ingredient in **efficin[®]** has been Recommended by Physicians and Pharmacists for many years
- Fewer Tablets Needed Because of the Extra Strength

Relief for the discomforts of
neuralgia and for temporary relief of minor pain due to
arthritis and rheumatism.

SAVE 50¢ NEXT PURCHASE OF
EXTRA STRENGTH **efficin[®]**
PAIN RELIEVER TABLETS



Present this coupon when you buy the 36 tablet bottle and your druggist or grocer will deduct 50¢ from the regular purchase price, subject to the terms below.
MR. RETAILER: You are authorized to act as our agent for redemption of this coupon. We will pay you the face value plus 5¢ handling provided you and the consumer have complied with the terms of the offer.
OFFER TERMS: This coupon is good only when redeemed by you from a consumer at time of purchasing specified brand. Any sales tax must be paid by consumer. Invoices showing your purchase of sufficient stock to cover all coupons redeemed must be shown on request. Void if taxed, restricted or prohibited by law, or if presented by any outside agencies, brokers, industrial or institutional users. Cash value, 1/20 of 1¢.
Send coupon to Warren-Teed Consumer Group, Division of Adria Laboratories, Inc., P.O. Box 2450, Columbus, Ohio 43215.
Offer limited to one coupon per specified product and size. Expires 6/30/84. This coupon good at your dealer's for one 36 tablet bottle of Extra Strength efficin[®] Pain Reliever Tablets.
Printed in USA

Complaint

103 F.T.C.

EXHIBIT H

Introducing

efficin.

Pain Reliever Tablets

Safe in More Ways Than One!



ON YOUR NEXT PURCHASE OF
SAVE 50¢ EXTRA STRENGTH **efficin** PAIN RELIEVER TABLETS

Present this coupon when you buy the 36 tablet bottle and your drug store or grocer will deduct 50¢ from the regular purchase price, subject to the terms below.

MR. RETAILER: You are authorized to act as our agent for redemption of this coupon. We will pay you the face value plus 5¢ handling provided you and the consumer have complied with the terms of the offer.

OFFER TERMS: This coupon is good only when redeemed by you from a consumer at time of purchasing specified brand. Any sales tax must be paid by consumer. Invoices showing your purchase of sufficient stock to cover all coupons redeemed must be shown on request. Void if taxed, restricted or prohibited by law or if presented by any outside agencies, brokers, industrial or institutional users. Cash value: 1/20 of 1¢.

Send coupon to: Warren Teed Consumer Products Laboratories, Inc., P.O. Box 2450, Columbus, Ohio 43214.

Offer limited to one coupon per specified product and size. Expires 6/30/84. This coupon good at your dealer's for one 36 tablet bottle of Extra Strength efficin Pain Reliever Tablets.

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EXHIBIT I

Introducing EXTRA STRENGTH **efficin**[®]

EFFICIN :30 SEC. TV



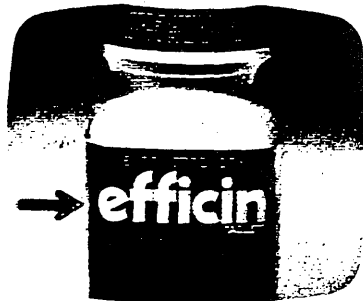
VO: ANNOUNCER

"Introducing extra strength efficin tablets. Fast pain relief that contains Magnesium Salicylate."



VO: ANNOUNCER

Efficin's active ingredient has been recommended by doctors and pharmacists for years and now it's available in a three way tamper resistant package.



VO: ANNOUNCER

Efficin's bottle is safely sealed in clear plastic wrap.



VO: ANNOUNCER

There's a safety seal under the cap.



VO: ANNOUNCER

The cap is child resistant.



VO: ANNOUNCER

Efficin... Extra strength pain relief. Safe in more ways than one.



Warren-Teed Consumer Products, Division of Adria Laboratories, Columbus, Ohio

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Adria Laboratories, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 5000 Post Road, in the City of Dublin, State of Ohio.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I

It is ordered, That respondent Adria Laboratories, Inc. a corporation, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, offering for sale, sale, or distribution of Efficin or any other over-the-

counter internal analgesic containing magnesium salicylate affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that the product contains no aspirin, or any other representation, directly or by implication, comparing the product's safety to any product containing aspirin, unless the following statement is clearly and prominently disclosed:

A. "Efficin (or other product's name) has side effects similar to aspirin."

B. If Efficin's (or other product's) label discloses that consumers should not take the product if they have stomach distress, ulcers or bleeding problems except under the direction and supervision of a physician, respondent may substitute the following statement for the disclosure required in Part I(A): "Efficin (or other product's name) is similar to aspirin. Read label including warnings."

C. If Efficin's (or other product's) package insert discloses that consumers should not take the product if they have stomach distress, ulcers or bleeding problems except under the direction and supervision of a physician, respondent may substitute the following statement for the disclosure required in Part I(A): "Efficin (or other product's name) is similar to aspirin. Read and save package insert including warnings."

D. Such other statement approved by the Federal Trade Commission in advance, or

E. Such other statement as respondent can demonstrate (based on consumer surveys whose design is adequate and previously approved by the Federal Trade Commission) will convey the same messages as conveyed by the statement in Parts I(A), I(B), or I(C) as applicable.

Provided, That it shall not violate this Part to distribute packages of Efficin that were fully packaged as of October 18, 1983, that do not contain a disclosure statement required by this Part.

II

A. *It is further ordered*, That respondent, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, labeling, packaging, offering for sale, sale, or distribution of any over-the-counter drug product affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, concerning the safety of such product or from comparing any such product to any product or products of one

or more competitors concerning safety, unless, at the time of such representation, respondent possesses and relies upon a reasonable basis for such representation, consisting of reliable and competent scientific evidence that substantiates each such representation.

B. To the extent the evidence of a reasonable basis consists of scientific or professional tests, analyses, research, studies or any other evidence based on expertise of professionals in the relevant area, such evidence shall be "reliable and competent" for purposes of Part II(A) only if those tests, analyses, research, studies, or other evidence are conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results.

III

It is further ordered, That respondent notify the Commission at least thirty (30) days prior to any proposed change in respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

IV

It is further ordered, That respondent shall forthwith distribute a copy of this order to each of its operating divisions involved in the marketing of over-the-counter drugs.

V

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

VI

It is further ordered, That, for the period of three years after it last disseminated the advertisements of the products covered by this order, respondent shall maintain accurate records:

1. Of all materials that were relied upon by respondent in disseminating any representation covered by this order.
2. Of all test reports, studies, surveys, or demonstrations in its

possession or control or of which it has knowledge that contradict any representation made by respondent that is covered by this order.

These records may be inspected by the staff of the Commission upon reasonable notice.

Commissioner Pertschuk dissented from failure to include an unfairness allegation in the complaint.

Modifying Order

103 F.T.C.

IN THE MATTER OF

AMERICAN HOME PRODUCTS CORPORATION

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket 8918. Final Order, September 9, 1981—Modifying Order June 7, 1984*

This order reopens the proceeding and modifies the Commission's order issued on September 9, 1981, (98 F.T.C. 136), *modified* April 8, 1983 (101 F.T.C. 698), *modified further* Feb. 7, 1984 (103 F.T.C. 57) so that its basic provisions are in parity with the Commission order in *Bristol-Myers Company*, [102 F.T.C. 21 (1983)] and *Sterling Drug, Inc.*, [102 F.T.C. 395 (1983)]. Under the modified order, the company must have a reasonable basis consisting of reliable scientific evidence for all therapeutic performance or safety claims. The previous order covered such claims only if they compared one product to another.

ORDER REOPENING THE PROCEEDING AND MODIFYING
CEASE AND DESIST ORDER

Respondent American Home Products Corporation in a "renewed request" filed on January 27, 1984, petitioned to reopen these proceedings and modify the Order. This request was placed on the public record for comment, with no comments filed.

On April 5, 1984, pursuant to discussion with Commission staff, respondent filed a proposed Order which was agreed to by staff. This proposed Order suggests changes in the Modified Order to Cease and Desist of April 8, 1983, as modified by Order of February 7, 1984. The proposed Order adds a new paragraph 1(A)(4) and substitutes new language for paragraphs 1(B), III, and IV. With these modifications the basic provisions of this Order will be in general parity with the Commission's Orders in *Bristol-Myers Company*, Docket No. 8917 [102 F.T.C. 21 (1983)] and *Sterling Drug, Inc.*, Docket No. 8919. [102 F.T.C. 395 (1983)]

The Commission being of the opinion that the public interest would be served by such reopening of the proceedings;

Now, therefore, it is ordered, That the proceedings in Docket No. 8918 be, and they hereby are, reopened; and

It is further ordered, That the Order in Docket No. 8918 be substituted as to respondent American Home Products Corporation by a modified Order as follows: