UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of	
CIBA-GEIGY CORPORATION, and	
CIBA SELF-MEDICATION, INC., corporations.	

DOCKET NO. 9279

COMPLAINT

)

The Federal Trade Commission, having reason to believe that Ciba-Geigy Corporation, and CIBA Self-Medication, Inc., corporations ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH ONE: Respondent Ciba-Geigy Corporation ("Ciba-Geigy") is a New York corporation with its principal office or place of business at 444 Saw Mill River Road, Ardsley, New York 10502.

Respondent CIBA Self-Medication, Inc. ("CIBA Self-Medication"), is a Delaware corporation with its principal office or place of business at 581 Main Street, Woodbridge, New Jersey 07095. CIBA Self-Medication is a wholly-owned subsidiary of Ciba-Geigy.

PARAGRAPH TWO: Respondents have manufactured, labeled, advertised, offered for sale, sold, and distributed drug products, including Doan's analgesic products, to the public. Doan's analgesic products are "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PARAGRAPH THREE: Ciba-Geigy acquired the Doan's analgesic product line in 1987. Between 1987 and 1994, Ciba-Geigy advertised and sold Doan's analgesic products through its CIBA Consumer Pharmaceuticals division. CIBA Self-Medication was incorporated in December 1994, at which time Ciba-Geigy transferred the assets of CIBA

Consumer Pharmaceuticals to CIBA Self-Medication. Since December 1994, CIBA Self-Medication has advertised and sold Doan's analgesic products.

PARAGRAPH FOUR: The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PARAGRAPH FIVE: Respondents have disseminated or caused to be disseminated advertisements for Doan's analgesic products, including, but not necessarily limited to, the attached Exhibits A - I. Respondents have disseminated these or substantially similar advertisements for at least eight years. These advertisements contain the following statements and depictions:

A. Doctors measure back pain by how far you can bend. Extra Strength Doan's is made for back pain relief with an ingredient these pain relievers don't have. [Depiction of large package of Doan's in front of smaller packages of Bayer, Advil and Tylenol] Doan's makes back pain go away. Extra Strength Doan's. The Back Specialist. [Superscript: The back specialist]

[Exhibit A: "Graph" 15-Second Television]

B. Lower back pain. Neck pain. Upper back pain. There are all kinds of back pain. Doan's relieves them all. With a special ingredient these brands don't have. [Depiction of large package of Doan's in front of smaller packages of Bayer, Advil and Tylenol]. Relieve back pain with Doan's, the Back Specialist. [Superscript: The Back Specialist.]

[Exhibit B: "Black & White Back" 15-Second Television]

C. Now. Back pain doesn't have to ruin another night's sleep. Introducing new Doan's P.M. Doan's starts with a unique pain reliever these brands don't have; [Depiction of large package of Doan's P.M and smaller packages of Tylenol, Bayer and Advil] [Superscript: Magnesium Salicylate] then adds a second ingredient to help you sleep. New Doan's P.M. For nighttime back pain. [Superscript: For Nighttime Back Pain]

[Exhibit C: "Ruin A Night's Sleep" 15-Second Television]

D. If nothing seems to help, try Doan's. It relieves back pain no matter where it hurts. Doan's has an ingredient these pain relievers don't have. [Depiction of large package of Doan's in front of smaller packages of Bayer, Aleve, Advil and Tylenol] [Superscript: Magnesium Salicylate]. Doan's. The Back Specialist. [Superscript: The Back Specialist]

[Exhibit D: "Activity - Pets" 15-Second Television]

E. There are hundreds of muscles in the back. Any one can put you in agony. That's when you need Doan's. *[Depiction of Doan's package on top of packages of Tylenol, Bayer, Aleve and Advil]*. Doan's has an ingredient the leading brands don't. It relieves back pain no matter where it hurts. There are hundreds of muscles in the back. *[Superscript: The Back Specialist]* Doan's relieves them all.

[Exhibit E: "Muscles" 15-Second Television]

F. Doan's. Made for back pain relief. With an ingredient these other pain relievers don't have. [Depiction of packages of Bayer, Tylenol, and Advil].

[Exhibit F: Print Advertisement]

G. Back pain is different. Why use these pain relievers? [Depiction of packages of Tylenol, Motrin, and Advil]. Doan's is just for back pain.

[Exhibit G: Print Advertisement]

H. BACK PAIN SUFFERERS[:] IT'S EASY TO SEE WHY YOU NEED DOAN'S. These are for all kinds of aches and pains. [Depiction of packages of Tylenol, Bayer, Motrin, and Advil, with a magnifying glass on the Tylenol package emphasizing Tylenol's labeling indications for use for "the temporary relief of minor aches, pains, headaches and fever."]. Doan's is just for back pain.

[Exhibit H: Print Advertisement]

I. WHY TREAT GENERAL ACHES? [Depiction of packages of Bayer, Tylenol, Advil, and Aleve].

> BACK PAIN NEEDS THE SPECIALIST [Depiction of packages of Regular Strength Doan's, Extra Strength Doan's, and Extra Strength Doan's P.M.].

DOAN'S. WITH A UNIQUE INGREDIENT THE OTHERS DON'T HAVE.

[Exhibit I: Print Advertisement]

PARAGRAPH SIX: Through the use of the statements and depictions contained in the advertisements referred to in PARAGRAPH FIVE, including but not necessarily limited to the advertisements attached as Exhibit A - I, respondents have represented, directly or by implication, that Doan's analgesic products are more effective than other analgesics, including Bayer, Advil, Tylenol, Aleve, and Motrin, for relieving back pain.

PARAGRAPH SEVEN: Through the use of the statements and depictions contained in the advertisements referred to in PARAGRAPH FIVE, including, but not necessarily limited to, the advertisements attached as Exhibits A - I, respondents have represented, directly or by implication, that at the time they made the representation set forth in PARAGRAPH SIX, respondents possessed and relied upon a reasonable basis that substantiated such representation.

PARAGRAPH EIGHT: In truth and in fact, at the time they made the representation set forth in PARAGRAPH SIX, respondents did not possess and rely upon a reasonable basis that substantiated such representation. Therefore, the representation set forth in PARAGRAPH SEVEN was, and is, false and misleading.

PARAGRAPH NINE: The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices and the making of false advertisements in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

NOTICE

Notice is hereby given to the respondents hereinbefore named that the twenty-sixth day of August, 1996, at 10:00 a.m. o'clock is hereby fixed as the time and the Federal Trade Commission Offices, Room 532-H, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under said Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the thirtieth (30th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admissions, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest these allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint provide a record basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceeding in this matter that the proposed order provisions as to Ciba-Geigy Corporation, and CIBA Self-Medication, Inc., corporations, might be inadequate to fully protect the consuming public, the Commission may order such further relief as it finds necessary or appropriate, including corrective advertising or other affirmative disclosure. Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations in the form of restitution and refunds for past, present, and future consumers and such other types of relief as are set forth in § 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for relief provided for in § 19(b) on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

ORDER

For purposes of this Order:

1. "Doan's" shall mean any over-the-counter analgesic drug, as "drug" is defined in the Federal Trade Commission Act, bearing the Doan's brand name, including, but not limited to, Regular Strength Doan's analgesic, Extra Strength Doan's analgesic, and Extra Strength Doan's P.M. analgesic.

2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

I.

IT IS ORDERED that respondents Ciba-Geigy Corporation, and CIBA Self-Medication, Inc., corporations, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Doan's or any other over-the-counter analgesic drug, in or affecting commerce, as "drug" and "commerce" are defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that such product is more effective than other over-the-counter analgesic drugs for relieving back pain or any other particular kind of pain, unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of Part I of this Order, "competent and reliable scientific evidence" shall include at least two adequate and well-controlled, doubleblinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, each of whom is qualified by training and experience to conduct such studies, independently of each other. IT IS FURTHER ORDERED that respondents Ciba-Geigy Corporation, and CIBA Self-Medication, Inc., corporations, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any over-the-counter analgesic drug in or affecting commerce, as "drug" and "commerce" are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, regarding such product's efficacy, safety, benefits, or performance, unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this Order, respondents, or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All materials that were relied upon in disseminating such representation; and
- B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

V.

IT IS FURTHER ORDERED that respondents shall:

A. Within thirty (30) days from the date of entry of this Order, provide a copy of this Order to each of their current principals, officers, directors and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order; and

B. For a period of ten (10) years from the date of entry of this Order, provide a copy of this Order to each of their future principals, officers, directors, and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order who are associated with them or any subsidiary, successor, or assign, within three (3) days after the person assumes his or her position.

VI.

IT IS FURTHER ORDERED that respondents shall notify the Commission at least thirty (30) days prior to any proposed change in their corporate structures, including, but not limited to, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or affiliates, or any other corporate change that may affect compliance obligations arising out of this Order.

VII.

IT IS FURTHER ORDERED that this Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; **provided**, **however**, that the filing of such a complaint will not affect the duration of:

- A. Any paragraph in this Order that terminates in less than twenty (20) years;
- B. This Order's application to any respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Paragraph as though the complaint was never filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

VIII.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days from the date of entry of this Order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed at Washington, D.C. this twenty-first day of June, 1996.

By the Commission, Commissioner Azcuenaga dissenting.

Donald S. Clark Secretary

SEAL

Attachment: Dissenting Statement of Commissioner Azcuenaga

[Exhibits A-I attached to paper copies, but not available in electronic form]