

Complaint

IN THE MATTER OF

LEINER HEALTH PRODUCTS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4035; File No. 0123039

Complaint, February 19, 2002--Decision, February 19, 2002

This consent order addresses claims on certain packaging and labeling for acetaminophen tablets produced by Respondent Leiner Health Products, Inc. that such products are all or virtually all made in the United States. The order, among other things, prohibits the respondent from misrepresenting the extent to which any non-prescription drug product containing an analgesic is made in the United States, while permitting the respondent to represent that such products are made in the United States as long as all, or virtually all, of the ingredients or component parts of such products are made in the United States and all, or virtually all, of the labor in manufacturing such products is performed in the United States. The order also permits the respondent to represent that a product containing imported active ingredient(s) is "Processed in the United States with Foreign Ingredients" when describing a product that has been "significantly processed" in the United States.

Participants

For the Commission: *Laura D. Koss, Walter C. Gross, Joni Lupovitz, Elaine D. Kolish and Keith Anderson.*

For the Respondent: *Harvey Applebaum, Covington & Burling.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Leiner Health Products, Inc. ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Delaware corporation with its principal office or place of business at 901 233rd Street, Carson, California 90745.

Complaint

2. Respondent has manufactured, labeled, offered for sale, sold, and distributed acetaminophen tablets to the public, including but not limited to private label acetaminophen brands.

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

4. Respondent has disseminated or has caused to be disseminated packaging and labeling for certain of its acetaminophen products, including but not necessarily limited to the attached Exhibits A through E. The packaging and labeling contain the following statements or depictions:

**A. Equate Extra Strength PM Nighttime Sleep
Aid/Pain Reliever, Exhibit A**

“Manufactured by Leiner Health Products Inc. . . .
[image of American flag] Made in the USA”

**B. Kirkland Non-Drowsy Day-time Cold/Flu Medicine
Soft Gels, Exhibit B**

“Distributed by: Leiner Health Products Inc. . . . **Made in
the U.S.A.**”

C. Target Non-Aspirin Extra Strength, Exhibit C

“Distributed by Dayton Hudson Corporation . . . Made in
U.S.A.”

**D. Member’s Mark Pain Reliever • Fever Reducer
Acetaminophen 500 mg, Exhibit D**

“Distributed by: SWC . . . Made in the U.S.A.”

Complaint

E. Safeway Extra Strength Pain Relief Tablets, Exhibit E

“DISTRIBUTED BY SAFEWAY INC. . . . PRODUCT OF U.S.A.”

5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that certain of its acetaminophen products are made in the United States, *i.e.*, that all, or virtually all, of the ingredients of such products are made in the United States, and that all, or virtually all, of the labor in manufacturing such products is performed in the United States.

6. In truth and in fact, a significant portion of the ingredients of certain of respondent’s acetaminophen products is, or has been, of foreign origin. The active ingredient, bulk acetaminophen compound, that respondent processed into acetaminophen tablets is or was made outside the United States. Therefore, the representation set forth in Paragraph 5 was, and is, false or misleading.

7. The acts and practices of respondent 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(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52.

THEREFORE, the Federal Trade Commission this nineteenth day of February 2002, has issued this complaint against respondent.

By the Commission.

Leinen Health Products
Exhibits

012 3039

Drug Facts

Active Ingredients (in each caplet):
 Acetaminophen 500 mg
 Diphenhydramine Hydrochloride 25 mg

Purposes:
 Pain Reliever/Fever Reducer
 Sleep Aid

Uses: For the temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

Warnings:
 Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.
 Do not use • With other products containing acetaminophen
 • If you have a breathing problem such as emphysema or chronic bronchitis
 • If you have glaucoma or difficulty in urination due to enlargement of the prostate gland.
 Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.
 When using this product • do not exceed recommended dosage
 • drowsiness will occur
 • Do not drive a motor vehicle or operate machinery
 • Do not use for more than 10 days • Avoid alcoholic beverages

equate

extra strength pm

NIGHTTIME SLEEP AID/PAIN RELIEVER

150
CAPLETS

Compare to Extra Strength Tylenol® PM
Caplets active ingredients*

NDC 59606-060-24

EQ81129AQ08
LHP016

LHP016

equate

extra strength pm

NIGHTTIME SLEEP AID/PAIN RELIEVER

150
CAPLETS

Compare to Extra Strength Tylenol® PM
Caplets active ingredients*

NDC 59606-060-24

USE ONLY IF INNER FOIL SEAL PRINTED "SEALED FOR YOUR PROTECTION" IS NOT BROKEN OR MISSING.
 Keep tightly closed. Store at room temperature between 15° and 30°C (59° and 86°F). Use by expiration date printed on package.

* This product is not manufactured or distributed by McNeil Consumer Products Company, distributor of Extra Strength Tylenol® PM. Tylenol® is a registered trademark of Ortho-Clinical Diagnostics, Inc.

MANUFACTURED BY
 LEIMER HEALTH PRODUCTS INC.
 CARSON, CA 90745 U.S.A.

EQ81129AQ08

Made in the USA
 SATISFACTION GUARANTEED
 BY REFUND OR EXCHANGE

Drug Facts (continued)

Stop use and ask a doctor • If this product is used for pain for more than 10 days
 • If fever persists for more than 3 days or gets worse
 • If redness or swelling is present, these could be signs of a serious condition
 • If symptoms persist or new ones occur
 • If sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.
Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions: Adults and children 12 years of age and over: 2 caplets at bedtime. Do not give to children under 12 years of age.

Inactive Ingredients: FD&C Blue No. 1, FD&C Blue No. 2, Hydroxypropyl Methylcellulose, Microcrystalline Cellulose, Polyethylene Glycol, Titanium Dioxide, and may also contain: Croscarmellose Sodium, Magnesium Stearate, Polydextrose, Polydextrose 80, Povidone, Pregelatinized Starch, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid, Tracellin.



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
 Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Federal medical attention is critical for adults as well as children if you do not notice the signs or symptoms.

Age Group	Frequency	Maximum Dose
Adults and children 12 years of age and over:	2 softgels with water every 4 hours	Not to exceed 8 softgels in 24 hours
Children 6 to under 12 years of age:	1 softgel with water every 4 hours	Not to exceed 4 softgels in 24 hours
Children under 6 years of age:	Consult a doctor	

Inactive Ingredients: D&G Yellow No. 10, Edible Ink, FD&C Red No. 40, FD&C Yellow No. 8, Gelatin, Glycerin, Polyethylene Glycol, Povidone, Propylene Glycol, Tropic Purifier, Purified Water, Sorbitol.

Store at room temperature between 15° and 30° (59° and 86°). Use by expiration date printed on package.
 Keep tablets in carton for better identification until used.
 *This product is not manufactured or distributed by Procter & Gamble, distributor of DayQuil® LiquidCaps®.
 DayQuil® and LiquidCaps® are registered trademarks of The Procter & Gamble Company.
 CF81744A008

Distributed by:
 Lannet Health Products Inc.
 Carson, CA 90745 1-800-774-2678
 Made in the U.S.A.



DAY-TIME
 Non-Drowsy
 Cold/Flu Medicine Softgels

KIRKLAND

ITEM #314005

Compare To The Active Ingredients Of DayQuil® LiquidCaps™

- ✓ Nasal Decongestant
- ✓ Pain Reliever - Fever Reducer
- ✓ Cough Suppressant

Pseudoephedrine / Acetaminophen / Dextromethorphan

DAY-TIME
 Non-Drowsy
 Cold/Flu Medicine Softgels

KIRKLAND

Compare To The Active Ingredients Of DayQuil® LiquidCaps™

- ✓ Nasal Decongestant
- ✓ Pain Reliever - Fever Reducer
- ✓ Cough Suppressant

Pseudoephedrine / Acetaminophen / Dextromethorphan

SAFETY SEALED. THIS PRODUCT PROTECTED WITH SEALED BUSTER UNITS. DO NOT USE IF ANY AIR ORPUSHES OUT FROM THE BUSTER.

Drug Facts

Active Ingredients (in each softgel)

Active Ingredients	Purpose
Pseudoephedrine HCl 30 mg	Nasal Decongestant
Acetaminophen 250 mg	Pain Reliever/Fever Reducer
Dextromethorphan HBr 10 mg	Cough Suppressant

Uses temporarily relieve symptoms due to the common cold/flu:
 • minor aches and pains • fever • headache • muscular aches
 • sore throat/pain • nasal congestion • cough

Warnings

Alcohol Warning: If you consume 2 or more alcoholic drinks each day, ask your doctor whether you should take acetaminophen or other pain reliever/fever reducers. Acetaminophen may cause liver damage.

(Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a health professional before taking this product. • with other products containing acetaminophen

Ask a doctor before use if you have:

- asthma
- chronic bronchitis
- cough associated with smoking
- diabetes
- heart disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- excessive phlegm (mucus)
- glaucoma or chronic cough
- emphysema
- thyroid disease

Stop use and ask a doctor:

- If nervousness, dizziness, or sleeplessness occur.
- If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting.
- If symptoms do not improve or are accompanied by fever that lasts more than 3 days, or if new symptoms occur.
- If cough persists for more than 7 days (adults) or 5 days (children), recurs, or is accompanied by rash or persistent headache. A persistent cough may be a sign of a serious condition.

Failure to follow these warnings could result in serious consequences.

Do not use for more than 7 days (for adults) or 5 days (for children).

KIRKLAND

Non-Drowsy

DAY-TIME

Cold/Flu Medicine Softgels

Pseudoephedrine / Acetaminophen / Dextromethorphan

- ✓ Nasal Decongestant
- ✓ Pain Reliever - Fever Reducer
- ✓ Cough Suppressant

DAY-TIME
 Non-Drowsy
 Cold/Flu Medicine Softgels

KIRKLAND

Compare To The Active Ingredients Of DayQuil® LiquidCaps™

- ✓ Nasal Decongestant
- ✓ Pain Reliever - Fever Reducer
- ✓ Cough Suppressant

Pseudoephedrine / Acetaminophen / Dextromethorphan

DAY-TIME
 Non-Drowsy
 Cold/Flu Medicine Softgels

KIRKLAND

Compare To The Active Ingredients Of DayQuil® LiquidCaps™

- ✓ Nasal Decongestant
- ✓ Pain Reliever - Fever Reducer
- ✓ Cough Suppressant

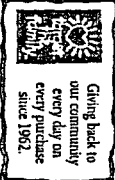
Pseudoephedrine / Acetaminophen / Dextromethorphan

CAUTION:
It is the user's responsibility to print a reasonable GPC code from either our return or your alternate GPC method.

Economy Size • Save • Economy Size • Save • Economy Size • Save • Economy Size • Save • Economy Size



094 01 0001



Unconditional Guarantee
If you are not completely satisfied with this product for any reason, simply return the unused portion for a complete refund.

NON ASPIRIN

PAIN RELIEVER/EVER REDUCER
ASPIRIN FREE
EASY TO SWALLOW
500 CAPLETS 500 MG EACH

COMPARE TO THE ACTIVE INGREDIENT OF TYLENOL EXTRA STRENGTH CAPLETS

USE ONLY IF INNER FOIL SEAL PRINTED "SEALED FOR YOUR PROTECTION" IS NOT BROKEN OR MISSING.

INDICATIONS: For the temporary relief of minor aches and pains associated with a cold or flu, headache, toothache, muscle aches, backache, the premenstrual and menstrual periods (dysmenorrhea), for the minor pain from arthritis, and to reduce fever.

DIRECTIONS: Adults and children 12 years of age and over: 2 caplets every 8 hours, while symptoms persist, not to exceed 8 caplets in 24 hours, or as directed by a doctor. Children under 12 years of age: Consult a doctor.

WARNINGS: Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. Do not use with other products containing acetaminophen.

ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain reliever/fever reducer. Acetaminophen may cause liver damage.

ACTIVE INGREDIENT: Each caplet contains: Acetaminophen 500 mg.

ALSO CONTAINS: Hydroxypropyl Methylcellulose, Povidone, Starch, Stearic Acid, May also contain: Croscarmellose Sodium, Hydroxypropyl Cellulose, Polyethylene Glycol, Polyorbate 80, Powdered Cellulose, Polyethylene Glycol, Sodium Starch Glycolate.

Keep tightly closed. Store at room temperature between 15° and 30°C (59° and 86°F). Use by expiration date printed on package.

***This product is not manufactured or distributed by McNeil Consumer Products Company, distributor of TYLENOL. TYLENOL is a registered trademark of McNeil Consumer Products Company, Monroeville, PA 15146. ©1989 DMC. All Rights Reserved. Made in U.S.A.**

10990006
Mfg. Date: 10/93

Leiner Health Products
In-house Graphics Department
810 E. 233 STREET • CARSON, CA 90745
VOICE (310) 835-8400 • FAX (310) 522-9180

COLORS				FONTS	
	PMS 100		PMS 100		PMS 100
	PMS 188		PMS 188		PMS 188
	PMS 070		PMS 070		PMS 070
	PMS 000		PMS 000		PMS 000
Free Panels:				Ingredient Panels:	
Uniflex (Family)				Uniflex (Family)	
Helvetica (Family)				Helvetica (Family)	
Utopia (Family)				Utopia (Family)	
Die Number:				Prepared by:	
0-107				Tom Nelson	
				January 13, 1989	
Full File Name: C:\PRODUCT\MOTOTARGET\GCPART\G9800.EPS				Printer: J. J. J. '94	
				CM, No. 11215	

*COLOR BREAK AND DIE LINES ARE FOR REFERENCE ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRINT PRODUCTION.



Member's MarkTM

Pain Reliever • Fever Reducer

ACETAMINOPHEN

500 mg



Compare to Extra Strength Tylenol[®]
active ingredient

Non Aspirin

EXTRA STRENGTH

500 Caplets

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 500 mg

Purposes

US • Temporarily relieves minor aches and pains associated with: cold, flu, headache, toothache, muscular aches, backache, the premenstrual and menstrual periods (dysmenorrhea), fever, arthritis, rheumatism • and to reduce fever.

Warnings

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use • with other products containing acetaminophen.

Drug Facts (continued)

Stop use and ask a doctor if this product is used for pain for more than 10 days or for fever for more than 3 days

• If pain or fever persists or gets worse • If new symptoms occur • or if redness or swelling is present, these could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

Age Group

Adults and children 12 years of age and over:	Children under 12 years of age:
2 caplets every 6 hours Not to exceed 8 caplets in 24 hours	Consult a doctor

Maximum Usage

Inactive Ingredients: Hydroxypropyl Methylcellulose, Povidone, Corn Starch, and Stearic Acid. May also contain: Carnauba Wax, Croscarmellose Sodium, 80, Powdered Cellulose, Polyethylene Glycol, Sodium Starch Glycolate, Talc, and Titanium Dioxide.

USE ONLY IF INNER FOIL SEAL PRINTED - SEALED FOR YOUR PROTECTION - IS NOT BROKEN OR MISSING.

Keep tightly closed. Store at room temperature between 15° and 30°C (59° and 86°F). Use by expiration date printed on package.

Distributed by: SWC
608 S.W. 8th Street, Bentonville, AR 72712
MM980080M06

Lot No. Exp. Date.



Leiner Health Products		810 E. 233 STREET • CARSON, CA 90745								
In-house Graphics Department		VOICE (310) 835-8400 • FAX (310) 522-9180								
Software:		☐ IBM ☒ MAC ☐ NO ☐ Illustrator 8								
Disk:		☐ YES ☒ NO								
Die Number:		3 X 8								
Prepared by:		NANCE								
OT 17 01										
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Colors		<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>								
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Job No.		Proofreader:								
MM-1000248										

CAUTION:

It is the vendors responsibility to print a scannable UPC code from either our artwork or your alternative UPC method.

USE ONLY IF INNER FOIL SEAL PRINTED "SEALED FOR YOUR PROTECTION" IS NOT BROKEN OR MISSING

INDICATIONS: For temporary relief of the pain of headache, sinusitis, colds, muscular aches, menstrual discomfort, toothaches and minor arthritis pain.

DIRECTIONS: Adults and children 12 years of age and over: 2 tablets every 6 hours while symptoms persist, not to exceed 8 tablets in 24 hours or as directed by a doctor. Drink a full glass of water with each dose. Children under 12 years of age: Consult a doctor.

WARNINGS: Children and teenagers who have or are recovering from chicken pox, measles, or flu should NOT use this product. It causes, worsens, or may trigger an early sign of Reye's syndrome, a rare but serious condition that can be fatal. Do not take this product for more than 10 days or for fever for more than 5 days. If pain persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor.

because these could be signs of a serious condition. Do not take this product if you are allergic to aspirin or if you have asthma unless directed by a doctor. If ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product. Do not take this product if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. It is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

PAIN RELIEVER

NDC 21130-310-14

COMPARE TO ACTIVE INGREDIENTS IN EXCEDRIN®

Extra Strength Pain Relief Tablets

- acetaminophen, aspirin and caffeine

50 COATED TABLETS

PAIN RELIEVER

NDC 21130-310-14

COMPARE TO ACTIVE INGREDIENTS IN EXCEDRIN®

Extra Strength Pain Relief Tablets

- acetaminophen, aspirin and caffeine

50 COATED TABLETS

25% BLACK OVERPRINTS
SOLID PMS 485

LHP010

SW95801BA08
LHP010

SAFEWAY

Extra Strength Pain Relief Tablets

50 COATED TABLETS

TAMPER EVIDENT BOTTLE
DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

This product is not manufactured or distributed by Bristol-Myers Products, distributor of Excedrin®. Excedrin® is a registered trademark of Bristol-Myers Squibb Company.

DISTRIBUTED BY SAFEWAY INC.
P.O. BOX 99, PLEASANTON, CA 94566-0099

PRODUCT OF U.S.A.

SAFETY SEAL

We appreciate your comments and ideas. Write to us or call toll free 1-888-SAFEWAY. Please include product code and lot number.

WWW.SAFEWAY.COM

ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen and aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

DRUG INTERACTION PRECAUTION: Do not take this product if you are taking a prescription drug for anti-coagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor.

ACTIVE INGREDIENTS: Each tablet contains: Acetaminophen 250 mg, Aspirin 250 mg, Caffeine 65 mg.

INACTIVE INGREDIENTS: Hydroxypropyl Methylcellulose, Polyethylene Glycol, Stearic Acid. May also contain: Carnauba Wax, Cellulose, FD&C Blue No. 1, Hydroxypropyl Cellulose, Maltodextrin, Microcrystalline Cellulose, Mineral Oil, Polyvinylpyrrolidone, Polyethylene Glycol, Silicon Dioxide, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Starch, Triphenyl Phosphate.

Keep tightly closed. Store at room temperature between 15° and 30°C (59° and 86°F). Use by expiration date printed on package.

Leiner Health Products
In-house Graphics Department

810 E. 233 STREET • CARSON, CA 90745
VOICE (310) 835-8400 • FAX (310) 522-9180

Path File Name: Q:\PRODUCTION\MOTCSAFEWAYART.W

*COLOR BREAK AND DIE LINES ARE FOR REF

Software(s):
Illustrator 8.0

WamNet:
☒ YES
☐ NO

Die Number:
LHP010

Prepared by:
Lois
11-30-00

Smallest Type: 5.5 pnt

SW-1000334 Proofreader:

the manufacturer's responsibility for a comparable GPC code in either our artwork or alternative UPC method.

ATELY REFLECT ACTUAL PRINT PRODUCTION.

Decision and Order

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 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 violations of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, and admission by the respondent of all the jurisdictional facts set forth in the draft 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, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, 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 violated the said Act, and that a 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 thirty (30) days, and having duly considered the comment filed thereafter by an interested person pursuant to Section 2.34 of its Rules, 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 Leiner Health Products, Inc. is a Delaware corporation with its principal office or place of business at 901 233rd Street, Carson, California 90745.

Decision and Order

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, Leiner Health Products, Inc., 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 manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any non prescription drug product containing an analgesic in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, shall not misrepresent, in any manner, directly or by implication, the extent to which any such product is made in the United States. For purposes of this Order, "drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55, and "analgesic" shall mean an agent used to alleviate pain.

PROVIDED, however, that a representation that any such product is made in the United States will not be in violation of this order so long as all, or virtually all, of the ingredients or component parts of such product are made in the United States and all, or virtually all, of the labor in manufacturing such product is performed in the United States.

PROVIDED FURTHER, that a representation that any such product containing imported active ingredient is "Processed in the United States with Foreign Ingredients" will not be in violation of this Order when such representation is true and is used to describe a product that has been significantly processed in the United States.

PROVIDED FURTHER, that nothing in the order shall prohibit respondent from depleting the inventory of packaging and

Decision and Order

labeling for such products bearing a marking or labeling otherwise prohibited by this order and existing on the date this order is signed, in the normal course of business, provided that no such existing inventory is shipped from respondent later than December 31, 2001.

II.

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

- A. All labeling, packaging, advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

III.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, shall deliver a copy of this order to all current and future officers and directors, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

Decision and Order

IV.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

V.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, shall, within sixty (60) days after the date of service 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 it has complied with this order.

VI.

This order will terminate on February 19, 2022, 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 this order if such complaint is filed after the order has terminated pursuant to this Part. Provided, further, that if such complaint is

Decision and Order

dismissed or a federal court rules that the respondent 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 Part as though the complaint had never been 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.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent Leiner Health Products, Inc. (“Leiner”).

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement’s proposed order.

This matter concerns “Made in U.S.A.” claims on packaging and labeling for Leiner’s acetaminophen tablets sold at retail bearing private brand names. The Commission’s complaint alleges that respondent misrepresented on packaging and labeling that certain of these products, manufactured for customers such as Wal-Mart, Costco, Target, and Safeway, are all or virtually all made in the United States. According to the complaint, these products are actually made with significant foreign content. The products’ active ingredient, bulk acetaminophen compound, that respondent processed into acetaminophen tablets, is or was made outside the United States. The imported bulk acetaminophen comprises a substantial percentage of total manufacturing costs and imparts the crucial analgesic quality to the OTC products at issue. The Commission’s complaint does not allege that all of Leiner’s private label acetaminophen brands or products are mislabeled, but only that certain products for certain customers have been improperly labeled.

The proposed consent order contains a provision that is designed to remedy the charges and to prevent the respondent from engaging in similar acts and practices in the future. Part I of the proposed order prohibits Leiner from misrepresenting the extent to which any non-prescription drug product containing an analgesic is made in the United States. The order defines

Analysis

“analgesic” as an agent used to alleviate pain. The proposed order would allow Leiner to represent that such products are made in the United States as long as all, or virtually all, of the ingredients or component parts of such products are made in the United States and all, or virtually all, of the labor in manufacturing such products is performed in the United States. The proposed order also would allow Leiner to represent that a product containing imported active ingredient(s) is “Processed in the United States with Foreign Ingredients” when describing a product that has been “significantly processed” in the United States.

The draft order also includes a provision that would allow Leiner to use its current packaging inventory until December 31, 2001.

Part II of the proposed order requires the respondent to maintain materials relied upon in disseminating any representation covered by the order. Part III of the proposed order requires the respondent to distribute copies of the order to certain company officials and employees. Part IV of the proposed order requires the respondent to notify the Commission of any change in the corporation that may affect compliance obligations under the order. Part V of the proposed order requires the respondent to file one or more compliance reports. Part VI of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

A & S PHARMACEUTICAL CORP.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4036; File No. 0123051

Complaint, February 19, 2002--Decision, February 19, 2002

This consent order addresses claims on certain packaging and labeling for aspirin tablets produced by Respondent A&S Pharmaceutical Corporation that such products are all or virtually all made in the United States. The order, among other things, prohibits the respondent from misrepresenting the extent to which any over-the-counter drug product is made in the United States, while permitting the respondent to represent that such products are made in the United States as long as all, or virtually all, of the ingredients or component parts of such products are made in the United States and all, or virtually all, of the labor in manufacturing such products is performed in the United States.

Participants

For the Commission: *Laura D. Koss, Walter C. Gross, Joni Lupovitz, Elaine D. Kolish and Keith Anderson.*

For the Respondent: *Dr. Arnold Lewis, pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that A & S Pharmaceutical Corporation ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Connecticut corporation with its principal office or place of business at 480 Barnum Avenue, Bridgeport, Connecticut 06608.