

Complaint

IN THE MATTER OF

PERRIGO COMPANY

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

Docket C-4039; File No. 0123121

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

This consent order addresses claims on certain packaging and labeling for aspirin, acetaminophen, and ibuprofen tablets produced by Respondent Perrigo Company 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: *George N. Grammas and George C. McKann, Gardner, Carton & Douglas.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Perrigo Company ("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:

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1. Respondent is a Michigan corporation with its principal office or place of business at 515 Eastern Avenue, Allegan, Michigan 49010.
2. Respondent has manufactured, labeled, offered for sale, sold, and distributed aspirin, acetaminophen, and ibuprofen tablets to the public, including but not limited to private label aspirin, acetaminophen, and ibuprofen 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 aspirin, acetaminophen, and ibuprofen products, including but not necessarily limited to the attached Exhibits A through D. The packaging and labeling contain the following statements or depictions:
 - A. **Equate Adult Low Strength 81 mg Enteric Coated Aspirin**
[Exhibit A]

“MANUFACTURED BY PERRIGO CO. . . . [image of American flag] Made in the USA”
 - B. **American Fare Ibuprofen Tablets [Exhibit B]**

“Made in U.S.A. for Kmart Corporation.”
 - C. **Target Brand Junior Strength Soft Chewable Tablets Acetaminophen [Exhibit C]**

“Distributed By Target Corporation . . . Made in USA”
 - D. **Safeway Junior Strength Non-Aspirin Acetaminophen Chewable Tablets [Exhibit D]**

Complaint

“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 aspirin, acetaminophen, and ibuprofen 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 aspirin, acetaminophen, and ibuprofen products is, or has been, of foreign origin. The active ingredients, bulk aspirin, acetaminophen, and ibuprofen compounds, that respondent processed into aspirin, acetaminophen, or ibuprofen tablets are or were 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.

Pearigo Company

Exhibits

0123121



VALUE SIZE
300 TABLETS

equate

NDC 0113-1538-87

enteric coated aspirin

ASPIRIN REGIMEN[®]
PAIN RELIEVER

81 mg
300 DELAYED RELEASE
ASPIRIN TABLETS

Compare to Bayer[®] Adult
Low Strength Aspirin active ingredient**

SEALED WITHIN PROTECTIVE FILM UNDER CAP FOR YOUR PROTECTION
ASPIRIN WARNING: IF YOU CONSUME 3 OR MORE ALCOHOLIC DRINKS EVERY DAY, ASK YOUR DOCTOR WHETHER YOU
SHOULD TAKE ASPIRIN OR OTHER PAIN RELIEVERS. THEY REDUCE ASPIRIN'S RISK OF STOMACH BLEEDING.
ONLY INFORMATION PRESENTED: DO NOT TAKE THIS PRODUCT IF YOU ARE TAKING A PRESCRIPTION DRUG FOR
HYPOBEMIPRAN (TRISOLIN[®]), A BLOOD THINNER, OR AN ANTICOAGULANT (INJECTED BY A DOCTOR).
THE ENTERIC COATING ON THIS PRODUCT IS DESIGNED TO ALLOW THE TABLET TO PASS THROUGH THE
STOMACH TO THE INTESTINE BEFORE IT DISSOLVES. PROVIDES PROTECTION AGAINST STOMACH UPSET.
BECAUSE OF ITS DELAYED ACTION, THIS PRODUCT WILL NOT PROVIDE FAST RELIEF OF HEADACHES, FLU,
OR OTHER SYMPTOMS REQUIRING IMMEDIATE RELIEF.
ACTIVE INGREDIENT: 81 MG ASPIRIN PER TABLET
INACTIVE INGREDIENTS: ACETYLATED MONOGLYCERIDES, COLLOIDAL SILICON DIOXIDE, CROSCARMELLLOSE,
SUCRALOSE, POLYVINYLPIRROLIDONE, HYDROXYMETHYLCELLULOSE PHOSPHATE, POTASSIUM LACTATE,
POLYACRYLATE, POLYACRYLAMIDE, MINERAL OIL, COCAINE POLYMER, POLYETHYLENE GLYCOL,
POLYACRYLATE, TITANIUM DIOXIDE.
STORAGE: ROOM TEMPERATURE (20°-25°C).
**EQUATE ENTERIC COATED ASPIRIN IS NOT MANUFACTURED OR DISTRIBUTED BY BAYER CORPORATION.
DISTRIBUTED BY: BAYER HEALTHCARE, A DIVISION OF BAYER CORP.



MANUFACTURED BY PERCO CO.
ALLIEN, WYOMING, U.S.A.



300 TABLETS
BY PERCO CO. OR EQUIV.

first discussing it with your doctor. IF YOU EXPERIENCE ANY SYMPTOMS WHICH ARE UNUSUAL OR SEEM UNRELATED TO THE CONDITION FOR WHICH YOU TOOK IBUPROFEN, CONSULT A DOCTOR BEFORE TAKING ANY MORE OF IT. Although ibuprofen is indicated for the same conditions as aspirin and acetaminophen, it should not be taken with them, except under a doctor's direction. Do not combine this product with any other analgesic containing product. 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 IBUPROFEN 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.

ACTIVE INGREDIENT: Each tablet contains Ibuprofen USP, 200 mg.
INACTIVE INGREDIENTS: Cellulose, Silicon Dioxide, Corn Starch, D&C Yellow #10 Aluminum Lake, FD&C Blue #2 Aluminum Lake, FD&C Red #40 Aluminum Lake, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Lactose Anhydrous, Magnesium Stearate, Monocrystalline Cellulose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide. Some of these ingredients may be sensitive to heat.



Made in USA for
Kmart Corporation
Troy, Michigan 48064

If you are not satisfied with this or any American Farm product, please call 1-800-642-7466.

IBUPROFEN TABLETS, contain Ibuprofen, a safe and effective pain reliever which has been prescribed by doctors for millions and is now available in non-prescription strength.



Modern Pain Medicine

Hot 877-642-7466
SEE WARNING
CHANGE

Ibuprofen
Tablets

Pain Reliever/Fever Reducer

Compare to active ingredient of Advil®

100 COATED TABLETS, 200 mg EACH



Junior strength, soft, chewable tablets

ACETAMINOPHEN

pain reliever/fever reducer
for ages 6-12
aspirin free - ibuprofen free

NDC 7 8134 3147

COMPARE TO ACTIVE
INGREDIENT OF ANAFLAN
ORAL SUSPENSION

Junior strength soft, chewable tablets

ACETAMINOPHEN

pain reliever/fever reducer
for ages 6-12

aspirin free - ibuprofen free

FRUIT FLAVOR

 **TARGET**
BRAND

24 TABLETS

160 MG

Unconditional Guarantee



This product is not a narcotic and does not
contain any alcohol. It is safe for use in
children and adults. It is not addictive.
Do not use if you are allergic to aspirin or
other salicylates. Do not use if you have
ever had an allergic reaction to aspirin or
other salicylates. Do not use if you have
ever had a severe allergic reaction to
aspirin or other salicylates.



SAFETY

NDC 21130-137-42

COMPARE TO ACTIVE INGREDIENT IN
JUNIOR STRENGTH TYLENOL®
FOR AGES 6-12*



OPEN OTHER END
NON-ASPIRIN

Junior Strength

Non-Aspirin

acetaminophen chewable tablets

- pain reliever • fever reducer
- for ages 6-12

Soft Chewable Tablets
Fruit Flavor

- aspirin free
- ibuprofen free



10 TABLETS
(100 mg each)

Junior Strength
Non-Aspirin

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. Proposed respondent is a Michigan corporation with its principal office or place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

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, Perrigo Company, 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.

Decision and Order

PROVIDED FURTHER, that this Part shall take effect for non-prescription drug products containing an imported analgesic on December 31, 2001, and shall take effect for all other non-prescription drug products containing an analgesic on March 31, 2002.

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 dismissed or a

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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 Perrigo Company. (“Perrigo”).

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 Perrigo’s aspirin, acetaminophen, and ibuprofen 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 Kmart, Wal-Mart, 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 ingredients, bulk aspirin, acetaminophen, or ibuprofen compounds, that respondent processed into aspirin, acetaminophen, or ibuprofen tablets, are or were made outside the United States. The imported bulk compounds comprise a substantial percentage of total manufacturing costs and impart the crucial analgesic quality to the OTC products at issue. The Commission’s complaint does not allege that all of Perrigo’s private label aspirin, acetaminophen, and ibuprofen brands or products are mislabeled, but only that certain products 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 Perrigo from misrepresenting the extent to which any non-prescription drug product containing an

Analysis

analgesic is made in the United States. The order defines “analgesic” as an agent used to alleviate pain. The proposed order would allow Perrigo 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 Perrigo 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 is effective on December 31, 2001, for OTC products containing an imported analgesic and on March 31, 2001, for all other OTC products containing an analgesic. These dates take into consideration the number of different products Perrigo produces and the time it will take to convert its stock without disrupting its supply of store brand goods to its retailer customers. Thus, the order is designed to end the mislabeling quickly while minimizing unnecessary burdens on Perrigo, its customers, and consumers of these products.

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

**KRIS A. PLETSCHKE, INDIVIDUALLY AND
DOING BUSINESS AS RAW HEALTH**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4040; File No. 0223070**Complaint, February 22, 2002--Decision, February 22, 2002*

This consent order addresses practices used by Respondent Kris A. Pletschke, individually and doing business as Raw Health, in marketing Colloidal Silver" – a dietary supplement allegedly containing submicroscopic particles of silver – intended to be taken for the cure and treatment of more than 650 diseases. The order, among other things, prohibits the respondent from misrepresenting any claims that Colloidal Silver – or any food, dietary supplement, drug, device, or health-related service or program – has been medically proven to kill disease-causing organisms or any number of infections in the body. The order also requires the respondent to possess and rely upon competent and reliable scientific evidence to substantiate representations that Colloidal Silver or any covered product (1) is effective in treating 650 diseases and health-related conditions; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatment of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or triple the normal dose of 260 parts per million, and is safe for children and pregnant and nursing women; or (7) has any health, performance, safety, or efficacy benefits. In addition, the order prohibits the respondent from misrepresenting, including by means of metatags, the existence, contents or interpretation of any test, study, or research. The order also requires the respondent to offer refunds to all of his past consumers and wholesale purchasers of Colloidal Silver, and to file a sworn affidavit with the Commission concerning his compliance with the refund provisions.

Participants

For the Commission: *James T. Rohrer, Cindy A. Liebes, and
Andrea L. Foster.*

For the Respondent: *Kris A. Pletschke, pro se.*