

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.

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 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.
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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 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.

Donald S. Clark
Secretary

ISSUED: February 19, 2002