WILLIAMS MULLEN

Direct Dial: 202.293.8123
jcannon@williamsmullen.com

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Office of the Secretary
Federal Trade Commission
Room 159
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Attention: Joni Lupovitz
Laura Koss
FTC/S 4302

Re: *Request for Comments Regarding Consent Decrees with Respect to Makers of Analgesics*

These comments are submitted on behalf of Rhodia, Inc., in response to the notices published in the Federal Register on November 14, 2001. 66 Fed. Reg. 57102-106. As set forth therein, the Federal Trade Commission has proposed entering consent agreements with five producers of over-the-counter analgesic medicines: A&S Pharmaceutical Corporation, Leiner Health Products, Inc., LNK International, Inc. Perrigo Company, and Pharmaceutical Formulations, Inc. Overall, the proposed consent decrees are appropriate and fair in the circumstances. Clarification of the labels used on over-the-counter analgesic medicines will assist consumers in making informed decisions between competing products.

There is, however, one potential problem with proposed decrees, as drafted. The decrees and accompanying notice do not address whether the absence of any origin label implicitly amounts to a claim of U.S. origin. Yet, because FDA requirements call for the address of the tablet producer to appear on the label, absence of any origin indication will almost certainly leave the impression that the products were manufactured at the address of the producer or distributor, regardless whether "significant" processing took place. Hence, the decrees should require either a "made in" or a processed in ..." label on all containers for retail sale.

The proposed consent decrees in part I recite that the makers of analgesic tablets and capsules shall not "misrepresent, directly or by implication, the extent to which any such product is made in the United States." Part I goes on to define the circumstances in

which the five producers may use a representation that the product was "made in the United States" or "Processed in the United States with Foreign Ingredients." However, the agreement does not expressly address the situation in which the producers make no representation concerning origin.

Under the Food, Drug and Cosmetic Act and the regulations of the Food and Drug Administration (FDA), makers and distributors of over-the-counter drugs, including analgesics, must identify the name an address of the distributor or "manufacturer," as defined therein. 21 U.S.C. § 502(b)(1); 21 C.F.R. § 201.1(a). Thus, the name and address of all five of the parties to the consent decrees (or the names and addresses of their customers/distributors) will appear on the commercial labels affixed to packages for sale at retail.

Most importantly, however, the operations performed by all five of the parties to this proceeding call for a label that states: "manufactured by ...." That is, pursuant to the FDA regulations, operations such as mixing, granulating, milling, tableting, encapsulating, coating, and filling into "dispensing containers," are deemed to be manufacturing. 21 C.F.R. § 201.1(b). The company that performs these steps is instructed by the FDA regulations to state "manufactured by ...." on its labels. Alternatively, if no qualifying language appears (i.e., only the name and address of the manufacturer is identified), the regulations provide that the identified company must be the "sole manufacturer" of the product or the product is mislabeled. 21 C.F.R. § 201.1(h)(2).

In the context of the FDA requirements for labeling, therefore, the appearance of the address of A&S Pharmaceutical Corporation, Leiner Health Products, Inc., LNK International, Inc. Perrigo Company, or Pharmaceutical Formulations, Inc., amounts to a legal representation that one of the five companies was the manufacturer.

There is an inherent tension between the FDA labeling requirement and the FTC's origin rules. To resolve that tension, therefore, the "manufacturer" for FDA purposes must disclose that it was not the manufacturer of the active ingredient—aspirin, acetaminophen or ibuprofen—identified on the label. Such disclosure is consistent with the policy goal of protecting consumers, as well as the recent regulations requiring registration and identification of foreign manufacturers. 66 Fed. Reg. 59,138 (November 27, 2001).

Prior FTC advice on this subject is case-dependent. For example, the FTC was asked whether a label including a U.S. address must also reference the Chinese components within the manufactured product. In response, the FTC stated that, "depending on the context, references to U.S. locations of headquarters or factories may, by themselves or in conjunction with other phrases or images, convey a claim of U.S. origin. . . . Staff believes, however, that a U.S. address alone, if it is no more prominent than necessary and if not accompanied by additional U.S. symbol or another element that

may convey a US. Origin claim, would not constitute a "Made in USA" claim." FTC Letter to Mr. Vasilios T. Nacopoulos, March 2, 1999.

In another context, however, the FTC stated that it considered the label "STAINLESS USA" to mean that surgical instruments were made in the United States. FTC Letter to Mr. Lawrence R. Pilon, January 11, 1999. In this case, the instruments were entirely or in major part stainless steel. Hence, the label would almost certainly lead a consumer to believe that it was the stainless steel that was made in the United States.

Similarly, here, the tablets and capsules in question are generic drugs, labeled "aspirin" or "acetaminophen" or "ibuprofen" *and subject to the labeling requirement of the FDA regulations.* Hence, the unqualified use of an address by regulation implies that the addressee was the sole manufacturer and that products were made in the United States at the identified location.

To dispel confusion and prevent the appearance created by an unqualified label, the proposed consent decrees should call for some type of origin label in all circumstances. Alternatively, if unchanged, the notice accompanying the final consent decrees could clarify that the absence of any origin statement, coupled with the identification of a U.S. address, would be misleading for purposes of 5 U.S.C. § 55.

Respectfully submitted,

James R. Cannon, Jr.
Special Counsel to Rhodia, Inc.