

**IN THE MATTER OF THE SECURITIES ACT,
R.S.O. 1990, c. S.5, AS AMENDED**

- AND -

**IN THE MATTER OF
NUVO RESEARCH INC. AND REBECCA E. KEELER**

**STATEMENT OF ALLEGATIONS
OF STAFF OF THE ONTARIO SECURITIES COMMISSION**

Staff of the Ontario Securities Commission (“Staff”) make the following allegations:

I. THE RESPONDENTS

1. Dimethaid Research Inc. (now Nuvo Research Inc. and hereinafter referred to as “Dimethaid”) is a reporting issuer in Ontario and in other Canadian provinces. At all relevant times, Dimethaid’s shares were listed and posted for trading on the Toronto Stock Exchange under the symbol DMX.
2. Dimethaid develops and manufactures pharmaceutical products. During the relevant period, one of Dimethaid’s two leading drugs was Pennsaid, a topical medication used to relieve pain and physical symptoms associated with primary knee osteoarthritis.
3. As of November 2003, Dimethaid had received regulatory approval to market Pennsaid in Canada, the United Kingdom, and certain European countries. Pennsaid was also being marketed and sold in certain Caribbean countries where approval to market was not required.

4. At all relevant times, Rebecca E. Keeler (“Keeler”) was the President, Chief Executive Officer (“CEO”) and Chairman of the board of directors of Dimethaid. Keeler was terminated on September 22, 2004 following the appointment of a new board of directors at Dimethaid’s annual general meeting (“AGM”) on September 21, 2004.

II. FACTS

A. Dimethaid’s New Drug Application and the Non-Approvable Letter

5. On August 7, 2001, Dimethaid filed a new drug application (the “New Drug Application”) with the Food and Drug Administration (“FDA”) to obtain approval to market Pennsaid in the United States.
6. One year later, by letter dated August 7, 2002, the FDA rejected Dimethaid’s application for Pennsaid as “not approvable” under FDA legislation on the basis that the clinical data presented by Dimethaid in support of the application was insufficient to determine if Pennsaid was safe and effective under the proposed conditions of use (the “Non-Approvable Letter”).
7. The particular deficiencies, as summarized in the Non-Approvable Letter, were with respect to the pharmacokinetic data, and the efficacy and safety data submitted by Dimethaid.
8. Upon receipt of the Non-Approvable Letter, Dimethaid provided notice to the FDA of its intention to file an amended New Drug Application for consideration.
9. The Non-Approval Letter expressly stated that any amendment by Dimethaid “should respond to all the deficiencies listed” and that the FDA would not process a partial reply by the company nor would the review clock be reactivated until all deficiencies have been addressed.

B. Design of Protocols and Additional Clinical Trials

10. Between August 2002 and November 2003, Keeler and others internally from Dimethaid met with representatives of the FDA to discuss and negotiate protocols for additional clinical trials.
11. In that period, two pharmacokinetic protocols and a safety and efficacy protocol were designed by Dimethaid in an effort to address the deficiencies outlined in the Non-Approvable Letter.
12. The pharmacokinetic protocols were submitted to the FDA by Dimethaid in December 2002 and found to be adequate. The studies were then carried out and completed by March 2003.
13. The safety and efficacy protocol, known as PEN-03-112 (“Protocol 112”), was provided to the FDA in July 2003 and finalized in November 2003. Two clinical trials were carried out in accordance with Protocol 112. The first trial, designated “Study 112”, began in February 2004 but was not complete until late 2005. The second trial, designated “Study 112E” began in March 2004 but was not complete until early 2006.
14. Approval of Dimethaid’s amended New Drug Application was dependent upon a totality of the data submitted by Dimethaid from Study 112 and Study 112E, data from the pharmacokinetic studies, and the data from Dimethaid’s original submissions under the New Drug Application.

C. Misleading Statements and Omission of Material Facts

15. On November 26, 2003 and June 24, 2004, Dimethaid filed short form prospectuses with the Commission in respect of two separate special warrant offerings (collectively referred to as the “Prospectuses”).
16. Each of the Prospectuses, certified by Keeler and others as containing full, true and plain disclosure of all material facts relating to the securities offered by the

Prospectuses, stated the following with respect to Pennsaid's status in the United States:

- (a) that "Pennsaid has completed all clinical studies in Canada and the United States"; and
 - (b) that "the Company's marketing approval for Pennsaid in the United States is being considered by the United States Food and Drug Administration".
17. Each of the Prospectuses failed to disclose the following facts which, in isolation or in combination, constituted material facts with respect to Pennsaid's status in the United States, specifically:
- (a) that, in August 2002, the New Drug Application was rejected as "not approvable" under FDA legislation;
 - (b) that the basis for the FDA's rejection of the New Drug Application was that the information presented by Dimethaid was insufficient to determine if Pennsaid was safe and effective under the proposed conditions of use;
 - (c) that the FDA would not consider an amended New Drug Application until all of the deficiencies identified by the FDA had been addressed by Dimethaid;
 - (d) that Dimethaid had taken steps to preserve its ability to file an amended New Drug Application for consideration by the FDA;
 - (e) that Dimethaid had not, as of the dates of the Prospectuses, filed an amended New Drug Application;
 - (f) from September 2002 to November 2003, that Dimethaid was in discussions with the FDA to develop study protocols necessary to address the deficiencies identified in the Non-Approvable Letter;
 - (g) that, by March 2003, Dimethaid had completed two studies to address the pharmacokinetic deficiencies identified by the FDA in the Non-Approvable Letter; and
 - (h) that, in July 2003, Dimethaid had submitted Protocol 112 (which was finalized in November 2003) to address the safety and efficacy deficiencies identified by the FDA in the Non-Approvable Letter.
18. With respect to Dimethaid's prospectus dated June 24, 2004, Dimethaid failed to disclose additional material facts with respect to the status of Pennsaid, specifically:

- (a) that Dimethaid had begun patient enrolment in February 2004 for Study 112;
- (b) that Dimethaid had begun patient enrolment in March 2004 for Study 112E.

D. Non-Disclosure to Dimethaid's Board of Directors and Misleading Statements to the Underwriters

- 19. At no time during the relevant period did Keeler disclose to Dimethaid's board of directors that it had received the Non-Approvable Letter or the consequences of the Non-Approvable Letter.
- 20. Furthermore, during the due diligence process for the offerings, Keeler made statements to Dimethaid's counsel and to counsel for the underwriters that were misleading or untrue by claiming that Dimethaid's last written communication with the FDA in respect of the New Drug Application was July 23, 2002 and, further, that Dimethaid was not aware of any unresolved issues for Pennsaid.

IV. CONDUCT CONTRARY TO ONTARIO SECURITIES LAW AND THE PUBLIC INTEREST

- 21. By failing to disclose the material facts set out in paragraphs 21 and 22, Dimethaid failed to make full, true and plain disclosure in the Prospectuses of material facts relating to the securities proposed to be distributed; specifically material facts with respect to status of its New Drug Application with the FDA for marketing approval of Pennsaid in the United States. In so doing, Dimethaid breached section 56 of the Act and acted in a manner contrary to the public interest.
- 22. As the sole officer and a director of Dimethaid, Keeler authorized, permitted or acquiesced in Dimethaid's filing of the Prospectuses that failed to provide full, true and plain disclosure of all material facts relating to the securities proposed to be distributed. In so doing, Keeler is deemed to have breached the Act pursuant to section 129.2 of the Act.

23. Keeler misled the directors of Dimethaid during the relevant period by withholding material information with respect to the Non-Approvable Letter. Furthermore, in the course of the underwriters' due diligence process, Keeler intentionally provided information that was misleading or untrue to Dimethaid's counsel and to counsel for the underwriters with respect to the status of the New Drug Application. In so doing, Keeler acted in a manner contrary to the public interest.
24. Such further and other allegations as Staff may advise and the Ontario Securities Commission may permit.

DATED at Toronto this 24th day of April, 2007.