

**Johnson & Johnson**  
CONSUMER COMPANIES, INC.

May 22, 2000

Ms. Tracy Riley  
Advisory Committee Secretary  
Dermatologic & Ophthalmologic  
Drug Products Advisory  
Committee Meeting  
5630 Fishers Lane  
Rockville, Maryland 20857

**NDA No. 21-026**  
**PEDIASTAT™**  
**(miconazole nitrate, USP 0.25%)**  
**Diaper Rash Ointment**

**ADVISORY COMMITTEE**  
**BRIEFING BOOK**

Dear Ms. Tracy Riley:

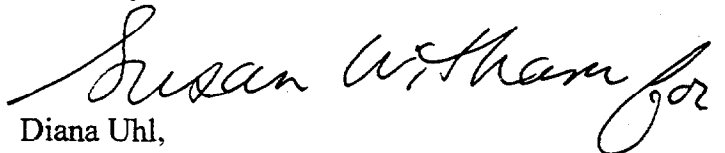
Reference is made to the Dermatological Drug Products Advisory Committee Meeting which is scheduled for June 30, 2000, in order to discuss the PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment, NDA No. 21-026. Johnson & Johnson Consumer Companies, Inc. (JJCCI) has enclosed fourteen copies of the PEDIASTAT Diaper Rash Ointment briefing book. The enclosed briefing book is clearly marked "AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION" in uppercase, bolded script.

Under a separate cover letter, fourteen additional copies of the briefing book were sent to Ms. Mille Wright, Project Manager, Division of Dermatologic and Dental Drug Products.

JJCCI would appreciate if you could forward to us any internal reports or memos that are generated in relation to the PEDIASTAT NDA which is being discussed on June 30<sup>th</sup>. If there are any comments or questions, please contact me at (908) 874-1402, FDA direct line (908) 874-1700, or fax number (908) 874-1118.

Thank you in advance for your assistance.

Sincerely,



Diana Uhl,  
Manager  
Regulatory Affairs

Attachments: 14 copies of the PEDIASTAT briefing book

**Johnson & Johnson**  
CONSUMER COMPANIES, INC.

May 22, 2000

Jonathan K. Wilkin, M.D.  
Director  
Division of Dermatologic and  
Dental Drug Products  
Office of Drug Evaluation V  
HFD-540  
Center for Drug Evaluation  
And Research  
Document Control Room N-115  
Food and Drug Administration  
9201 Corporate Boulevard  
Rockville, MD 20850

**NDA No. 21-026**  
**PEDIASTAT™**  
**(miconazole nitrate, USP 0.25%)**  
**Diaper Rash Ointment**

**GENERAL CORRESPONDENCE:**  
**Copies of the Advisory Committee**  
**Briefing Book**

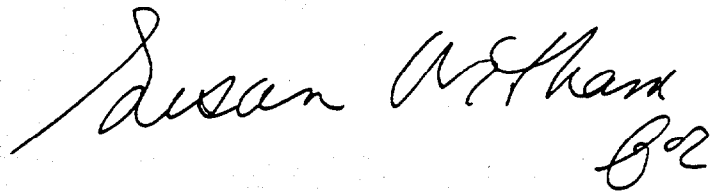
Dear Dr. Wilkin:

Reference is made to the Dermatologic Drugs Advisory Committee Meeting which is scheduled for June 30, 2000, in order to discuss the PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment, NDA No. 21-026. Johnson & Johnson Consumer Companies, Inc. (JJCCI) would like to inform the Division that fourteen copies of the PEDIASTAT Diaper Rash Ointment briefing book were sent directly to Ms. Mille Wright, Project Manager. Under a separate cover letter, fourteen copies of the briefing book were also sent to Ms. Tracy Riley, secretary for the Advisory Committee Meeting. The briefing book is clearly marked in uppercase, bolded script "AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION."

The Advisory Committee Meeting is quickly approaching and we would like to remind the Division that we have not yet received the questions which will be proposed to the advisory committee members. JJCCI would appreciate if the Division could communicate these questions to us as early as possible or the possibility of having a teleconference in order to discuss what the Division may be planning to ask at this meeting so that we can plan accordingly.

We would appreciate the Division's cooperation with this matter. If there are any comments or questions, please contact me at (908) 874-1402, FDA direct line (908) 874-1700, or fax number (908) 874-1118.

Sincerely,

A handwritten signature in cursive script that reads "Susan Williams" with a large, stylized initial "S" and "W". To the right of the signature, there are handwritten initials "DU".

Diana Uhl  
Manager,  
Regulatory Affairs

Cc: Fourteen copies of the briefing book and this cover letter were sent to Ms. Mille Wright, Project Manager, Division of Dermatologic and Dental Drug Products