[redacted] To: [redacted]>
cc:
12/04/2005 11:57 AM Subject: Re: PROTOPIC

Dear [redacted]
Thank you for your letter of 11th April 2005 in which you advised of the withdrawal of your application to register Protopic. Our records will be updated.

You also enclosed a separate letter on your potential resubmission.

Here are some comments:
New studies: these will help to define conventional and general safety but not specific risks. For example, studies on photodamaged skin, adequately power by size and by duration to detect various malignancies. You are conducting longer term epidemiological studies to attend to this and these data would be of interest.

Skin selectivity statement: this is false and misleading. the local dose is high and it risks local infections and tumours and, I presume, solar keratoses. Moreover, it relies on spurious toxicokinetic and pharmacokinetic arguments. The high local exposure to the immune system is why it works and may also be why Protopic might be a problem.

Who can prescribe: A non-significant change that has no practical effect.

Comparative trials: the text will be informed by the outcome of the evaluation.

Change of terminology: the evaluator will be asked to comment. I assume that both sets of terminology are compatible with CIOMS data presentation requirements.

Yours sincerely,

[redacted]

[redacted]

[redacted] To: [redacted]
cc:
Subject: PROTOPIC
11/04/2005 09:08 AM

Dear [redacted]

Thank you for your advice with PROTOPIC. I have had contact with [redacted] and we have together decided to withdraw the file. I will write to you at DSEB today about this

Best Regards,

[redacted]

Ref: RA.05.173
File Ref: TAC 01 04

11 April 2005

JANSSEN-CILAG
A Johnson & Johnson Company

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RECEIVED
12 APR 2005
DSEB

[redacted]
Drug Safety and Evaluation Branch
136 Narrabundah Lane
Symonston ACT 2609

Dear [redacted]

PROTOPIC (Tacrolimus) Ointment. Applic No. 2004/266/5

Janssen Cilag wishes to advise their decision to withdraw this file, following receipt of your advice

Yours Sincerely,

[redacted]

[redacted]
Biotechnology Manager, Janssen Cilag

Posted.
Person has been notified.

[redacted]
12 APR 2005

Head c205

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