

**From:** [REDACTED]  
**Sent:** Fri Mar 18 2005 14:50:09 EST  
**To:** carmen bozic/cambridge/biogen@biogenidec;  
**Subject:** Fw: BG00012: [REDACTED]

----- Forwarded by [REDACTED] on 03/18/2005 02:49 PM -----

[REDACTED]  
20-Dec-2004 10:32 AM

To  
BG-12 Program Team, [REDACTED], John  
O'Gorman/Cambridge/Biogen@BiogenIdec, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

cc  
[REDACTED]  
[REDACTED]  
Ratna Lingamaneni/Cambridge/Biogen@BiogenIdec, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

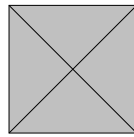
Subject  
BG00012: Official Pre-IND Meeting Minutes from FDA

Enclosed please find the "official" minutes from the Pre-IND meeting held with FDA on November 23, 2005. Although the minutes are quite similar to the draft comments received on November 19th, there are several differences...based primarily on the discussion that took place during the meeting.

Please review the minutes carefully and notify me of any significant differences in understanding regarding the meeting outcome. Comments are due on Tuesday, January 4, 2005.

If you have any questions or require additional information, please let me know ASAP.

Thanks





Food and Drug Administration  
 Center for Drug Evaluation and Research  
 Office of Drug Evaluation ODE V

**FACSIMILE TRANSMITTAL SHEET**

**DATE:** December 8, 2004

<b>To:</b> [REDACTED]	<b>From:</b> Frank H. Cross, Jr., M.A., CDR Senior Regulatory Management Officer
<b>Company:</b> Biogen Idec	Division of Division of Dermatologic & Dental Drug Products
<b>Fax number:</b> 617-679-3170	<b>Fax number:</b> (301) 827-2075/2091
<b>Phone number:</b> 617-679-6459	<b>Phone number:</b> (301) 827-2063
<b>Subject:</b> Facsimile Transmission of Pre-IND Meeting Minutes for PIND 69, 852, BG00012	

**Total no. of pages including cover:** 17

**Document to be mailed:**  YES  NO

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**Document to be mailed:**  YES  NO

Please find attached to this facsimile transmission our minutes of our November 23, 2004, Pre-IND Meeting for your PIND 69,852, BG00012, for psoriasis.

Please call me when you have received this facsimile transmission.

Thank you.

Sincerely,

Frank H. Cross, Jr., M.A., MT (ASCP)  
 CDR, USPHS Commissioned Corps  
 Senior Regulatory Management Officer and IT Liaison  
 Division of Dermatologic and Dental Drug Products  
 Office of Drug Evaluation V  
 Center for Drug Evaluation and Research  
 U.S. Food and Drug Administration  
 Ph.# 301-827-2063/2020  
 Fax.# 301-827-2075/2091  
 E-mail: [crossf@cder.fda.gov](mailto:crossf@cder.fda.gov)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

PIND 69,852

Biogen Idec

Attention: [REDACTED]

14 Cambridge Center  
Cambridge, MA 02142

Dear [REDACTED]:

Please refer to your Pre-Investigational New Drug Application (PIND) file for BG00012 for psoriasis.

We also refer to the meeting between representatives of your firm and the FDA on November 23, 2004. The purpose of the meeting was to discuss the pre-clinical and early clinical plans.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, please contact Frank Cross, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

*(See appended electronic signature page)*

Jonathan Wilkin, M.D.  
Division Director  
Division of Dermatologic and Dental Drug  
Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

Enclosure

PIND 69,852 11/23/04 meeting

Meeting Date: November 23, 2004  
Meeting ID# 14024

Time: 9:30 a.m.

Location: S300

BG00012

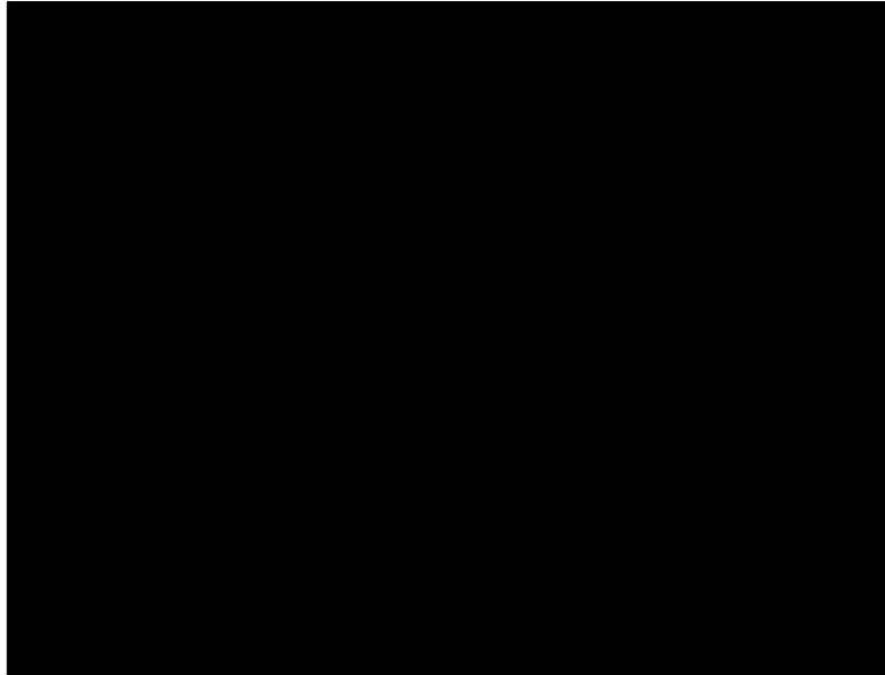
Indication: Treatment of psoriasis

Sponsor: Biogen Idec

Pre-IND Meeting

Meeting Chair: Jonathan K. Wilkin, M.D.

Meeting Recorder (CSO/Project Manager): Frank H. Cross, Jr., M.A., CDR



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