

Bhatt, Kalyani

om: Bhatt, Kalyani
Sent: Monday, April 08, 2002 11:51 AM
To: 'walton_thomas@allergan.com'
Subject: NDA 21-184 S-002 Tazarotene/Allergan

Tom could you please send us a word attachment for label for 002 and the approved label for 001 via email.
Thanks,
Kalyani

**APPEARS THIS WAY
ON ORIGINAL**

Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Monday, April 08, 2002 1:04 PM
To: 'Bhatt, Kalyani'
Subject: RE: Tazorac

Hi Kalyani.

What is this question in reference to? The Integrated Summary of Safety or Benefits and Risks or one of the clinical studies? Please provide more specific information.

Also, I received your labeling request and will forward the labeling to you shortly.

Thanks, Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Monday, April 08, 2002 9:06 AM
To: 'walton_thomas@allergan.com'
Subject: FW: Tazorac

Tom could you address Dr. Huene's request?

Please provide information on the adverse reactions of the skin and appendages that were considered to be severe in the two studies. The index for the electronic version states that these are in Appendix 3.0, but this Appendix is not provided.

"IRAPPS34 <allergan.com>" made the following annotations on 04/08/02 09:12:46

[INFO] -- Access Manager:
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"WorldSecure Server <cder.fda.gov>" made the following

annotations on 04/08/02 13:04:32

INFO] -- Access Manager:

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**APPEARS THIS WAY
ON ORIGINAL**

Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Friday, February 08, 2002 2:25 PM
To: 'Rumbaugh_Trudy'
Subject: RE: PK-01-012

Thanks Trudy.
Kalyani

-----Original Message-----

From: Rumbaugh_Trudy [mailto:Rumbaugh_Trudy@Allergan.com]
Sent: Thursday, February 07, 2002 4:01 PM
To: 'Bhatt, Kalyani'
Cc: Walton_Thomas; Rumbaugh_Trudy; Yu_Dale; Yu_Steve; Sefton_John
Subject: RE: PK-01-012
Importance: High

Hello Kalyani,
Here is the requested information from this PK report:

A new table (Table 2A) has been generated to summarize linear regression analyses results relating tazarotenic acid concentrations (ng/mL) to blood sampling time, and amount of tazarotene cream applied in patients with photodamaged skin receiving tazarotene cream 0.1% to the face once-daily up to 24 weeks.

Results based on both observed and log-transformed tazarotenic acid concentrations at weeks 2, 12, and 24 have been provided.

The detailed SAS outputs have also been provided in attached Appendix 5.

The regression results indicate a possible correlation between tazarotenic acid plasma concentration and amount of cream applied, and a lack of correlation between tazarotenic acid plasma concentration and the blood sampling time.

Please let me know if you need any further assistance.

Zhiling Yu, Ph.D.
Principal Scientist
<<Table_2a.doc>> <<Table_2a.pdf>> <<Appendix5.doc>>
<<Appendix5.pdf>>

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Wednesday, February 06, 2002 11:48 AM
To: 'rumbaugh_trudy@allergan.com'
Cc: 'walton_thomas@allergan.com'
Subject: PK-01-012

Hi Trudy and Tom

> The following table is copied from the Allergans' submission of the report (PK-01-012). Could you please add data and comments from asma . tazarotenic acid concentration versus blood sampling time and versus the

> amount of tazarotene cream 0.1% applied regression analysis.
> Thanks,
Kalyani

Table 2. Summary of linear regression analyses results relating
> tazarotenic acid concentrations to age, body weight, and body surface
area
> of patients with photodamaged skin receiving tazarotene cream 0.1% to
the
> face once-daily up to 24 weeks
>
> Dependent Variable Independent Variable p-value for the slope
> tazarotenic acid at week 2 age 0.0228 (N = 55)
> tazarotenic acid at week 12 age 0.0308 (N = 54)
> tazarotenic acid at week 24 age 0.0555 (N = 50)
> tazarotenic acid at week 2 body weight 0.7598 (N = 55)
> tazarotenic acid at week 12 body weight 0.7344 (N = 54)
> tazarotenic acid at week 24 body weight 0.6318 (N = 50)
> tazarotenic acid at week 2 body surface area 0.5079 (N = 55)
> tazarotenic acid at week 12 body surface area 0.6491 (N = 54)
> tazarotenic acid at week 24 body surface area 0.6904 (N = 50)
>
>

"IRAPPS34 <allergan.com>" made the following
annotations on 02/06/02 11:56:01

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[INFO] -- Access Manager:

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(I was successfully decrypted unless otherwise noted.

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"WorldSecure Server <cder.fda.gov>" made the following
annotations on 02/07/02 16:01:36

[INFO] -- Access Manager:

This message was sent from Allergan across the internet in encrypted
format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Friday, February 08, 2002 2:20 PM
To: 'Rumbaugh_Trudy'
Subject: RE: Information request for clinical reviewer Dr. Huene: TAZ CREAM PH OTODAMAGE (NDA 21-184/S-002)

Thanks Trudy.
K

-----Original Message-----

From: Rumbaugh_Trudy [mailto:Rumbaugh_Trudy@Allergan.com]
Sent: Thursday, February 07, 2002 4:38 PM
To: 'Bhatt, Kalyani'
Cc: Walton_Thomas; Stern_Katherine; Sefton_John; Rumbaugh_Trudy;
Lin_Thomas; Lew-Kaya_Deborah
Subject: Information request for clinical reviewer Dr. Huene: TAZ CREAM
PH OTODAMAGE (NDA 21-184/S-002)
Importance: High

Dear Kalyani,
As per the voice mail you and Dr. Huene left on 2/4/02 which concerns patients who were discontinued due to AEs. Here are tables that have been created for the two pivotal studies -033 and -034, as you requested, which we hope you will find useful. As is noted in the footer for the biostats generated table, all adverse events are reported for patients who discontinued the study due to adverse events, even though a particular adverse event may not necessarily have lead to the patient discontinuation (the specific AE for which a patient was discontinued was not captured on the CRFs).

<<033 and 034 AE List.txt>>

Please view the 2 tables below in "page layout" to read the titles in the header.

<<033C AE incidence table for FDA.doc>>
<<034C AE incidence table for FDA.doc>>

We recognize and very much appreciate Dr. Huene's efforts to expedite the review of this file, so please don't hesitate to request something further if she would find it helpful.

Kind regards,
Trudy

"WorldSecure Server <cder.fda.gov>" made the following annotations on 02/07/02 16:38:41

[INFO] -- Access Manager:
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Bhatt, Kalyani

From: Rumbaugh_Trudy [Rumbaugh_Trudy@Allergan.com]
Sent: Thursday, February 07, 2002 4:38 PM
To: 'Bhatt, Kalyani'
Cc: Walton_Thomas; Stern_Katherine; Sefton_John; Rumbaugh_Trudy; Lin_Thomas; Lew-Kaya_Deborah
Subject: Information request for clinical reviewer Dr. Huene: TAZ CREAM PH OTODAMAGE (NDA 21-184/S-002)

Importance: High



033 and 034 AE List.txt



033C AE incidence
table for FD...



034C AE incidence
table for FD...

Dear Kalyani,

As per the voice mail you and Dr. Huene left on 2/4/02 which concerns patients who were discontinued due to AEs. Here are tables that have been

created for the two pivotal studies -033 and -034, as you requested, which

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(the specific AE for which a patient was discontinued was not captured on the CRFs).

<033 and 034 AE List.txt>>

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Kind regards,
Trudy

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From: Rumbaugh_Trudy [Rumbaugh_Trudy@Allergan.com]
Sent: Thursday, February 07, 2002 4:01 PM
To: 'Bhatt, Kalyani'
Cc: Walton_Thomas; Rumbaugh_Trudy; Yu_Dale; Yu_Steve; Sefton_John
Subject: RE: PK-01-012

Importance: High



Table_2a.doc



Table_2a.pdf



Appendix5.doc



Appendix5.pdf

Hello Kalyani,

Here is the requested information from this PK report:

A new table (Table 2A) has been generated to summarize linear regression analyses results relating tazarotenic acid concentrations (ng/mL) to blood sampling time, and amount of tazarotene cream applied in patients with photodamaged skin receiving tazarotene cream 0.1% to the face once-daily up to 24 weeks.

Results based on both observed and log-transformed tazarotenic acid concentrations at weeks 2, 12, and 24 have been provided.

The detailed SAS outputs have also been provided in attached Appendix 5.

The regression results indicate a possible correlation between tazarotenic acid plasma concentration and amount of cream applied, and a lack of correlation between tazarotenic acid plasma concentration and the blood sampling time.

Please let me know if you need any further assistance.

Zhiling Yu, Ph.D.
Principal Scientist

<<Table_2a.doc>> <<Table_2a.pdf>> <<Appendix5.doc>>
<<Appendix5.pdf>>

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Wednesday, February 06, 2002 11:48 AM
To: 'rumbaugh_trudy@allergan.com'
Cc: 'walton_thomas@allergan.com'
Subject: PK-01-012

Hi Trudy and Tom

> The following table is copied from the Allergans' submission of the
> report (PK-01-012). Could you please add data and comments from
plasma
> tazarotenic acid concentration versus blood sampling time and versus
the
> amount of tazarotene cream 0.1% applied regression analysis.

Thanks,
Kalyani

> Table 2. Summary of linear regression analyses results relating
> tazarotenic acid concentrations to age, body weight, and body surface
> area
> of patients with photodamaged skin receiving tazarotene cream 0.1% to
> face once-daily up to 24 weeks

| > Dependent Variable | Independent Variable | p-value | for the slope |
|-------------------------------|----------------------|---------|---------------|
| > tazarotenic acid at week 2 | age | 0.0228 | (N = 55) |
| > tazarotenic acid at week 12 | age | 0.0308 | (N = 54) |
| > tazarotenic acid at week 24 | age | 0.0555 | (N = 50) |
| > tazarotenic acid at week 2 | body weight | 0.7598 | (N = 55) |
| > tazarotenic acid at week 12 | body weight | 0.7344 | (N = 54) |
| > tazarotenic acid at week 24 | body weight | 0.6318 | (N = 50) |
| > tazarotenic acid at week 2 | body surface area | 0.5079 | (N = 55) |
| > tazarotenic acid at week 12 | body surface area | 0.6491 | (N = 54) |
| > tazarotenic acid at week 24 | body surface area | 0.6904 | (N = 50) |

"IRAPPS34 <allergan.com>" made the following
annotations on 02/06/02 11:56:01

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[INFO] -- Access Manager:
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"WorldSecure Server <cder.fda.gov>" made the following
annotations on 02/07/02 16:01:36

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format and was successfully decrypted, unless otherwise noted.

Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Wednesday, February 06, 2002 2:48 PM
To: 'rumbaugh_trudy@allergan.com'
Cc: 'walton_thomas@allergan.com'
Subject: PK-01-012

Hi Trudy and Tom

The following table is copied from the Allergans' submission of the report (PK-01-012). Could you please add data and comments from plasma tazarotenic acid concentration versus *blood sampling time* and versus the *amount of tazarotene cream 0.1% applied* regression analysis.

Thanks,
Kalyani

TABLE 2. SUMMARY OF LINEAR REGRESSION ANALYSES RESULTS RELATING TAZAROTENIC ACID CONCENTRATIONS TO AGE, BODY WEIGHT, AND BODY SURFACE AREA OF PATIENTS WITH PHOTODAMAGED SKIN RECEIVING TAZAROTENE CREAM 0.1% TO THE FACE ONCE-DAILY UP TO 24 WEEKS

| Dependent Variable | Independent Variable | p-value for the slope |
|-----------------------------|-----------------------------|------------------------------|
| tazarotenic acid at week 2 | age | 0.0228 (N = 55) |
| tazarotenic acid at week 12 | age | 0.0308 (N = 54) |
| tazarotenic acid at week 24 | age | 0.0555 (N = 50) |
| tazarotenic acid at week 2 | body weight | 0.7598 (N = 55) |
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| tazarotenic acid at week 12 | body surface area | 0.6491 (N = 54) |
| tazarotenic acid at week 24 | body surface area | 0.6904 (N = 50) |

Bhatt, Kalyani

Jm: Bhatt, Kalyani
Sent: Monday, February 04, 2002 9:08 AM
To: 'Walton_Thomas'
Subject: RE: NDA 21-184/S-002 TRADE NAME

Good Morning Tom,
This has to be submitted formally. The accent over the changes the whole pronunciation and Office of Drug Safety will review this.
Thanks,
Kalyani

-----Original Message-----
From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, February 01, 2002 5:38 PM
To: 'Bhatt, Kalyani (e-mail)'
Cc: Rumbaugh_Trudy
Subject: NDA 21-184/S-002 TRADE NAME
Importance: High

Hi Kalyani:

Our marketing group has told me they want an accent mark over the in as shown.

Therefore, it will be:

 (tazarotene) Cream 0.1%

Does this need to be formally submitted or can you just attach this e-mail to the prior submission?

Please let me know.

Thank you,

Thomas W. Walton
Pharmaceutical Regulatory Affairs
@ Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cder.fda.gov>" made the following annotations on 02/01/02 17:38:31

[INFO] -- Access Manager:
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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Monday, February 04, 2002 9:07 AM
To: Bhatt, Kalyani
Subject: Out of Office AutoReply: NDA 21-184/S-002 TRADE NAME

I am out of the office; returning February 11, 2002. I will be checking my voicemail periodically, but not e-mail.

"WorldSecure Server <cder.fda.gov>" made the following annotations on 02/04/02 09:15:22

[INFO] -- Access Manager:
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APPEARS THIS WAY
ON ORIGINAL

Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Friday, February 01, 2002 5:38 PM
To: 'Bhatt, Kalyani (e-mail)'
Cc: Rumbaugh_Trudy
Subject: NDA 21-184/S-002 TRADE NAME

Importance: High

Hi Kalyani:

Our marketing group has told me they want an accent mark over the in as shown.

Therefore, it will be:

 (tazarotene) Cream 0.1%

Does this need to be formally submitted or can you just attach this e-mail to the prior submission?

Please let me know.

Thank you,

Thomas W. Walton
Pharmaceutical Regulatory Affairs
Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cder.fda.gov>" made the following annotations on 02/01/02 17:38:31

[INFO] -- Access Manager:

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Bhatt, Kalyani

om: Bhatt, Kalyani
Sent: Friday, February 01, 2002 1:41 PM
To: 'Walton_Thomas'
Subject: RE: NDA 21-184 S002

Yes I got it and forwarded to the reviewers.
K

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, February 01, 2002 12:38 PM
To: 'Bhatt, Kalyani'
Subject: RE: NDA 21-184 S002

Hi Kalyani:

I will request a copy from our Pharmacokinetics group.

Did you get the adverse events tables sent last night?

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
lton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cdcr.fda.gov]
Sent: Friday, February 01, 2002 9:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

Hi Tom

Could you please submit report of the study PK-01-012? Dr. Ghosh is interested in knowing the vehicle control data.

Thanks,
Kalyani

"IRAPPS34 <allergan.com>" made the following annotations on 02/01/02 09:28:21

[INFO] -- Access Manager:
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"WorldSecure Server <cdcr.fda.gov>" made the following annotations on 02/01/02 12:37:44

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**APPEARS THIS WAY
ON ORIGINAL**

Bhatt, Kalyani

om: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Friday, February 01, 2002 12:53 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: FW: NDA 21-184 S002



PK-01-012.doc

Hi Kalyani:

See below for the report in MS Word.

Sincerely,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Yu_Steve
Sent: Friday, February 01, 2002 9:38 AM
To: Walton_Thomas; Yu_Dale
Cc: Tang-Liu_Diane
Subject: RE: NDA 21-184 S002

<<PK-01-012.doc>> Hi Tom,

The report is attached.

Zhiling

-----Original Message-----

From: Walton_Thomas
Sent: Friday, February 01, 2002 9:35 AM
To: Yu_Dale; Yu_Steve
Subject: FW: NDA 21-184 S002

Hi Yu boys. FDA would like an MS Word copy of PK-01-012. Could you please send me one?

Thanks,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cdcr.fda.gov]
Sent: Friday, February 01, 2002 9:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

Hi Tom

Could you please submit report of the study PK-01-012? Dr. Ghosh is interested in knowing the vehicle control data.

Thanks,
Alyani

"IRAPPS34 <allergan.com>" made the following annotations on 02/01/02 09:28:21

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[INFO] -- Access Manager:

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"WorldSecure Server <cder.fda.gov>" made the following annotations on 02/01/02 12:53:18

[INFO] -- Access Manager:

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Friday, February 01, 2002 12:22 PM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

Hi Tom

Could you please submit report of the study PK-01-012? Dr. Ghosh is interested in knowing the vehicle control data.

Thanks,
Kalyani

**APPEARS THIS WAY
ON ORIGINAL**

Bhatt, Kalyani

Jm: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Thursday, January 31, 2002 7:02 PM
To: 'Bhatt, Kalyani'
Cc: Rumbaugh_Trudy
Subject: RE: NDA 21-184 S002



FDA AE Request
012802 033C.txt...



FDA AE Request
012802 034C.txt...

Hi Kalyani:

Here is your request. As they were not submitted in the NDA, I will submit them officially.

<<FDA AE Request 012802 033C.txt>> <<FDA AE Request 012802 034C.txt>>

Of course, these are not MS Word documents and MS Word versions are not available.

As I mentioned to you earlier this week, I will be at the DIA CMC meeting in Philadelphia next week. If you have any questions or requests next week, please send them to Trudy (714.246.4292) in my absence.

Sincerely,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Monday, January 28, 2002 12:55 PM
To: 'walton_thomas@allergan.com'
Subject: NDA 21-184 S002

Hi Tom,
Could you please find a list of the adverse events which caused the discontinuations in Studies 33 and 34 for Dr. Huene.
Thanks Kalyani

"IRAPPS34 <allergan.com>" made the following annotations on 01/28/02 13:02:45

[INFO] -- Access Manager:
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"WorldSecure Server <cder.fda.gov>" made the following
annotations on 01/31/02 19:01:47

[INFO] -- Access Manager:
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format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Wednesday, January 30, 2002 8:48 AM
To: 'Walton_Thomas'
Subject: RE: NDA 21-184 S002

Thank you Tom.
Kalyani

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Tuesday, January 29, 2002 8:07 PM
To: 'Bhatt, Kalyani'
Subject: RE: NDA 21-184 S002

Hi Kalyani:

I just got this now. Financial disclosures for Drs. — Fisher and Funicella.

<<Financia.pdf>>

Sincerely,

Tom
Thomas W. Walton
Pharmaceutical Regulatory Affairs
Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Monday, January 28, 2002 12:45 PM
To: 'walton_thomas@allergan.com'
Subject: NDA 21-184 S002

Hi Tom
Could we get the financial disclosure forms for Drs. Fisher, — and Funicella. ?

> Thanks.

>

Kalyani

"IRAPPS34 <allergan.com>" made the following annotations on 01/28/02 12:50:42

[INFO] -- Access Manager:
This message was sent from FDA across the Internet in Encrypted format
& was successfully decrypted unless otherwise noted.

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"WorldSecure Server <cder.fda.gov>" made the following
notations on 01/29/02 20:07:16

[INFO] -- Access Manager:

This message was sent from Allergan across the internet in encrypted
format and was successfully decrypted, unless otherwise noted.

Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Tuesday, January 29, 2002 8:07 PM
To: 'Bhatt, Kalyani'
Subject: RE: NDA 21-184 S002



Financia.pdf

Hi Kalyani:

I just got this now. Financial disclosures for Drs. — Fisher and Funicella.

<<Financia.pdf>>

Sincerely,

Tom
Thomas W. Walton
Pharmaceutical Regulatory Affairs
@ Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Monday, January 28, 2002 12:45 PM
To: 'walton_thomas@allergan.com'
Subject: NDA 21-184 S002

Hi Tom
Could we get the financial disclosure forms for Drs. Fisher, — and Funicella. ?

> Thanks.
>
Kalyani

"IRAPPS34 <allergan.com>" made the following annotations on 01/28/02 12:50:42

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"WorldSecure Server <cder.fda.gov>" made the following annotations on 01/29/02 20:07:16

[INFO] -- Access Manager:

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Tuesday, January 29, 2002 6:35 PM
To: 'Bhatt, Kalyani'
Subject: RE: NDA 21-184 S002

Hi Kalyani:

We are working on both your requests (Financial Disclosure and Adverse Event data). Several clinical people are out of the office monitoring studies, so it may be a couple of days for some of the information to get to Regulatory Affairs.

I will keep you updated.

Sincerely,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----
From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Monday, January 28, 2002 12:55 PM
To: 'walton_thomas@allergan.com'
Subject: NDA 21-184 S002

Hi Tom ,
Could you please find a list of the adverse events which caused the discontinuations in Studies 33 and 34 for Dr. Huene.
Thanks Kalyani

"IRAPPS34 <allergan.com>" made the following annotations on 01/28/02 13:02:45

[INFO] -- Access Manager:
This message was sent from the FDA across the Internet in Encrypted format and was successfully decrypted unless otherwise noted.

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"WorldSecure Server <cder.fda.gov>" made the following annotations on 01/29/02 18:35:00

[INFO] -- Access Manager:

This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Monday, January 28, 2002 3:55 PM
To: 'walton_thomas@allergan.com'
Subject: NDA 21-184 S002

Hi Tom ,
Could you please find a list of the adverse events which caused the discontinuations in Studies 33 and 34 for Dr. Huene.
Thanks Kalyani

APPEARS THIS WAY
ON ORIGINAL

Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Wednesday, January 16, 2002 6:49 PM
To: 'Bhatt, Kalyani (e-mail)'; 'Ko_Hon Sum (FDA)'
Subject: Clinical Safety Commitment for NDA 21-184

| | | | | | |
|---|---|--|---|---|---|
|  CSR 190168-045C text (sections... |  PK-01-128.doc |  14.0 Tables Figures and Graphs... |  14.3.1 Display of Adverse Even... |  14.3.2 Listing of Deaths Other... |  14.4 Supplemental Demographic ... |
|  14.5 Supplemental Efficacy Dat... |  14.6 Supplemental Safety Data ... |  15.0 Reference List.doc |  16.1.4 List and Description of... |  16.1.6 List of Patients per Te... |  16.1.7 Randomization Scheme an... |
|  16.1.8 Audit Certificates.doc |  16.1.9.1 Documentation of Stat... |  16.1.10 Laboratory Methods.doc... |  16.1.11 Study Publications.do... |  16.1.12 Reference Publication... |  16.2 Patient Data Listings (t... |
|  16.2.2 Protocol Deviations.doc... |  16.2.3 Patents Excluded from ... |  16.2.5 Compliance and/or Drug C... |  16.3.1 CRFs for Deaths Other S... |  16.3.2 Other CRFs Submitted (I... |  16.4 Individual Patient Data L... |

Hi

Kalyani and Dr. Ko:

Here is the MS Word version of the bone safety study in psoriasis patients 12-17 years old. All pieces that are available in MS Word are included. This study will be formally submitted to IND [redacted] and cross-referenced NDA 21-184. If you have any questions, please let me know.

Sincerely,
Tom

<<CSR 190168-045C text (sections 1-13).doc>>
<<PK-01-128.doc>>
<<14.0 Tables Figures and Graphs (title list).doc>> <<14.3.1
Display of
Adverse Events.doc>> <<14.3.2 Listing of Deaths Other Serious and
Certain Other Significant Adverse Events .doc>> <<14.4
Supplemental
Demographic Data .doc>>
<<14.5 Supplemental Efficacy Data .doc>> <<14.6
Supplemental
Safety Data .doc>> <<15.0 Reference List.doc>> <<16.1.4 List
and
Description of Investigators.doc>> <<16.1.6 List of Patients per
Test
Drug Batch.doc>> <<16.1.7 Randomization Scheme and Codes.doc>>
<<16.1.8 Audit Certificates.doc>> <<16.1.9.1
Documentation of
Statistical Methods.doc>> <<16.1.10 Laboratory Methods.doc>>
<<16.1.11 Study Publications.doc>> <<16.1.12 Reference
Publications.doc>> <<16.2 Patient Data Listings (title list).doc>>
<<16.2.2 Protocol Deviations.doc>> <<16.2.3 Patients
Excluded

from the Efficacy Analysis.doc>> <<16.2.5 Compliance and/or Drug
Concentration Data.doc>> <<16.3.1 CRFs for Deaths Other Serious
Adverse Events and Withdrawals for Adverse Events.doc>>
16.3.2

Other CRFs Submitted (list of patients).doc>> <<16.4 Individual
Patient

Data Listings (title list).doc>>

Thomas W. Walton

Pharmaceutical Regulatory Affairs

at Allergan, Inc.

Tel: 714.246.4470

Fax: 714.246.4272

Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cder.fda.gov>" made the following
annotations on 01/16/02 18:50:21

[INFO] -- Access Manager:

This message was sent from Allergan across the internet in encrypted
format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Thursday, January 10, 2002 1:11 PM
To: 'Walton_Thomas'
Subject: RE: Taz Crm S-002/MS Word sections of 190168-033C

Importance: High

Thanks Tom.
Kalyani

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Thursday, January 10, 2002 1:04 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: Taz Crm S-002/MS Word sections of 190168-033C

Hi Kalyani:

Here are the sections that are available in MS Word. Let me know if you require anything else. Hope you are having a good week. The other sections are other programs and scanned in documents. I am getting the protocol MS Word version later today from clinical and will send that to you then.

Sincerely,

 n
 <<CSR 190168-033C (open-label) text.doc>>
<<PK-01-082.doc>>
 <<14.0 Tables Figures and Graphs (title list).doc>> <<14.4
Supplemental
Demographic Data.doc>> <<14.5 Supplemental Efficacy Data.doc>>
 <<14.6 Supplemental Safety Data.doc>> <<14.7 Drug
Measurements.doc>> <<16.1.9 Documentation of Statistical
Methods.doc>>

Thomas W. Walton
Pharmaceutical Regulatory Affairs
@ Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

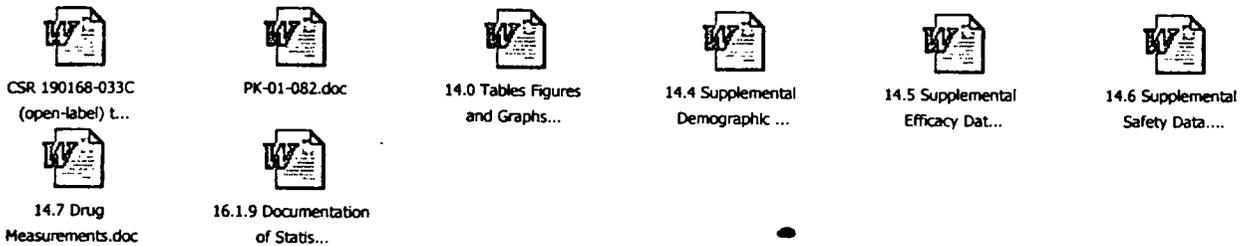
"WorldSecure Server <cderr.fda.gov>" made the following annotations on 01/10/02 13:04:58

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Thursday, January 10, 2002 1:04 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: Taz Crm S-002/MS Word sections of 190168-033C



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Here are the sections that are available in MS Word. Let me know if you require anything else. Hope you are having a good week. The other sections are other programs and scanned in documents. I am getting the protocol MS Word version later today from clinical and will send that to you then.

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Tom

<<CSR 190168-033C (open-label) text.doc>>
<<PK-01-082.doc>>
<<14.0 Tables Figures and Graphs (title list).doc>> <<14.4
Supplemental
Demographic Data.doc>> <<14.5 Supplemental Efficacy Data.doc>>
<<14.6 Supplemental Safety Data.doc>> <<14.7 Drug
Measurements.doc>> <<16.1.9 Documentation of Statistical
Methods.doc>>

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cdcr.fda.gov>" made the following annotations on 01/10/02 13:04:58

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Monday, January 07, 2002 5:09 PM
To: 'Bhatt, Kalyani'
Subject: RE: Study 190168-033C Files for NDA 21-184

Hi Kalyani:

I thought I already did, but I will send it again.

Sincerely,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Monday, January 07, 2002 9:58 AM
To: 'Walton_Thomas@allergan.com'
Subject: FW: Study 190168-033C Files for NDA 21-184

Tom,
Could you please send this report .
Thanks,
Kalyani

-----Original Message-----

From: Ghosh, Tapash
Sent: Monday, January 07, 2002 12:55 PM
To: Bhatt, Kalyani
Subject: RE: Study 190168-033C Files for NDA 21-184

Hi K:

Thanks. Can you please request the sponsor to send the original report of this study like they did for 038C? The original report contains all the data.

-----Original Message-----

From: Bhatt, Kalyani
Sent: Monday, January 07, 2002 12:45 PM
To: Ghosh, Tapash
Subject: FW: Study 190168-033C Files for NDA 21-184

Here it is.
K

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Thursday, December 13, 2001 12:46 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: FW: Study 190168-033C Files for NDA 21-184

Hi Kalyani:

Here are the main Word files for Study 190168-033C that you requested from the Taz Crm Efficacy Supplement (S-2). I will still send you the drug monitoring/pharmacokinetic component that was included as part of this study.

You also requested Study 190168-038C which was the Clinical Pharmacokinetic study that was part of S-2. I will send that one shortly, too.

Sincerely,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

-----Original Message-----

From: Abernethy_Kristen
Sent: Thursday, December 13, 2001 9:27 AM
To: Walton_Thomas
Subject: 033C Files

I'm not sure if you'll be able to open these, let me know.....

<<CSR 190168-033C (open-label) text.doc>> <<14.4 Supplemental Demographic Data.doc>> <<14.5 Supplemental Efficacy Data.doc>>
<<14.6 Supplemental Safety Data.doc>> <<14.7 Drug Measurements.doc>>

"WorldSecure Server <cder.fda.gov>" made the following annotations on 12/13/01 12:47:30

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[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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"IRAPPS34 <allergan.com>" made the following annotations on 01/07/02 10:04:15

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[INFO] -- Access Manager:
This message was sent from FDA across the Internet in Encrypted format and was successfully decrypted unless otherwise noted.

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WorldSecure Server <cdcr.fda.gov>" made the following
annotations on 01/07/02 17:08:17

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted
format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Friday, January 04, 2002 3:32 PM
To: 'Walton_Thomas'
Subject: RE: Attachements and PK repotr: NDA 21-184/S-002

Importance: High

Thanks again. K

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, January 04, 2002 2:21 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: Attachements and PK repotr: NDA 21-184/S-002

<<PK-01-009.doc>> <<14.0 Tables Figure and Graphs.doc>> <<14.2
Efficacy Data.doc>> <<15.0 References.doc>> <<16.1.4 List
and
Description of Investigators.doc>> <<16.1.6 Listings of Patients
Per
Test Drug Batch.doc>>

<<16.1.7.1 Original Randomization for All Potential
Subjects.doc>>

<<16.1.9 Documentation of Statistical Methods.doc>>

These are all of the pieces of the study available in MS Word, the rest
consists of scanned documents, .pdfs or other formats.

Any problems, let me know,
Have a good weekend,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cderr.fda.gov>" made the following
annotations on 01/04/02 14:22:21

[INFO] -- Access Manager:

This message was sent from Allergan across the internet in encrypted
format and was successfully decrypted, unless otherwise noted.

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hatt, Kalyani

From: Bhatt, Kalyani
Sent: Friday, January 04, 2002 3:31 PM
To: 'Walton_Thomas'
Subject: RE: Microsoft Pieces for Study 190168-038C for NDA 21-184/S-002

Importance: High

Thanks Tom.
Kalyani

-----Original Message-----
From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, January 04, 2002 2:18 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: Microsoft Pieces for Study 190168-038C for NDA 21-184/S-002

Hi Kalyani:

This will take several e-mails due to the large amount of data. Here is the protocol and CSR. Attachments and PK report to follow.

<<190168-038C PR Amend#1.doc>> <<190168-038C (sec
1.0).doc>> <<190168-038C (Sec 2.0).doc>> <<CSR 190168-038C.doc>>

Thomas W. Walton
Pharmaceutical Regulatory Affairs
à Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cder.fda.gov>" made the following annotations on 01/04/02 14:18:14

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Friday, January 04, 2002 2:21 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: Attachements and PK repotr: NDA 21-184/S-002



PK-01-009.doc



14.0 Tables Figure and Graphs....



14.2 Efficacy Data.doc



15.0 References.doc



16.1.4 List and Description of...



16.1.6 Listings of Patients Pe...



16.1.7.1 Original Randomizatio...



16.1.9 Documentation of Statis...

<<PK-01-009.doc>> <<14.0 Tables Figure and Graphs.doc>> <<14.2
Efficacy Data.doc>> <<15.0 References.doc>> <<16.1.4 List
and
Description of Investigators.doc>> <<16.1.6 Listings of Patients
Per
Test Drug Batch.doc>>

 <<16.1.7.1 Original Randomization for All Potential
Subjects.doc>>
 <<16.1.9 Documentation of Statistical Methods.doc>>

These are all of the pieces of the study available in MS Word, the rest consists of scanned documents, .pdfs or other formats.

If you have any problems, let me know,
Have a good weekend,

Tom

Thomas W. Walton
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@ Allergan, Inc.
Tel: 714.246.4470
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Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cder.fda.gov>" made the following annotations on 01/04/02 14:22:21

[INFO] -- Access Manager:

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Friday, January 04, 2002 2:18 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: Microsoft Pieces for Study 190168-038C for NDA 21-184/S-002



190168-038C PR
Amend#1.doc



190168-038C (sec
1.0).doc



190168-038C (Sec
2.0).doc



CSR 190168-038C.doc

Hi Kalyani:

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<<190168-038C PR Amend#1.doc>> <<190168-038C (sec
1.0).doc>> <<190168-038C (Sec 2.0).doc>> <<CSR 190168-038C.doc>>

Thomas W. Walton
Pharmaceutical Regulatory Affairs
& Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

"WorldSecure Server <cder.fda.gov>" made the following annotations on 01/04/02 14:18:14

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Thursday, December 13, 2001 12:46 PM
To: 'Bhatt, Kalyani (e-mail)'
Subject: FW: Study 190168-033C Files for NDA 21-184



CSR 190168-033C
(open-label) L...



14.4 Supplemental
Demographic ...



14.5 Supplemental
Efficacy Dat...



14.6 Supplemental
Safety Data...



14.7 Drug
Measurements.doc

Hi Kalyani:

Here are the main Word files for Study 190168-033C that you requested from the Taz Crm Efficacy Supplement (S-2). I will still send you the drug monitoring/pharmacokinetic component that was included as part of this study.

You also requested Study 190168-038C which was the Clinical Pharmacokinetic study that was part of S-2. I will send that one shortly, too.

Sincerely,

Tom

Thomas W. Walton
Pharmaceutical Regulatory Affairs
Allergan, Inc.
Tel: 714.246.4470
Fax: 714.246.4272
Walton_Thomas@Allergan.com <mailto:Walton_Thomas@Allergan.com>

-----Original Message-----

From: Abernethy_Kristen
Sent: Thursday, December 13, 2001 9:27 AM
To: Walton_Thomas
Subject: 033C Files

I'm not sure if you'll be able to open these, let me know.....

<<CSR 190168-033C (open-label) text.doc>> <<14.4 Supplemental
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<<14.6 Supplemental Safety Data.doc>> <<14.7 Drug Measurements.doc>>

"WorldSecure Server <cderr.fda.gov>" made the following annotations on 12/13/01 12:47:30

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Thursday, November 15, 2001 1:17 PM
To: 'walton_thomas@allergan.com'
Subject: FW: Tazorac SN2

-----Original Message-----

From: Ghosh, Tapash
Sent: Thursday, November 15, 2001 1:06 PM
To: Bhatt, Kalyani
Subject: Tazorac SN2

Hi Kalyani:

Please request the sponsor to send me MS Word version of the following items:

Summary
Full report of Study 033C
Full report of study 038C

I tried to convert PDF form from EDR to MS Word. However there are some glitches.

Thanks,

Tapash

033c pp 1-581

034c pp 1-586

036c pp 1-233

037c pp 1-122

**APPEARS THIS WAY
ON ORIGINAL**

Bhatt, Kalyani

From: Bhatt, Kalyani

Sent: Friday, October 26, 2001 1:57 PM

To: 'walton_thomas@allergan.com'

Subject: FW: NDA 21-184 S-002 Tradename(tazarotene)/Photodamage

Good Morning Trudy and Tom,

We are in the process of changing the medical reviewer for this supplement. Would it be possible to send us a paper copy of the following material. Please call me today.

Thanks,

Kalyani

A. Cover letter

B. Application Text

Item 1. TOC

Item 2. Labeling Section

Labeling History pp 1-2

Proposed Labeling pp 1-17

Item 3. Summary Section pp 1-138

Item 8. Clinical Section

Background and Overview pp 1-71

Integrated Summary of Efficacy pp 1-290

Integrated Summary of Safety pp 1-272

Integrated Summary of Risks and Benefits pp 1-9

013 pp 1-95

025c pp 1-488

Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Wednesday, October 24, 2001 9:04 AM
To: 'allergan.com'
Cc: Ko, Hon Sum; Huene, Phyllis A
Subject: NDA 21-184 S-002 Tradename(tazarotene)/Photodamage
Importance: High

Good Morning Trudy and Tom,

We are in the process of changing the medical reviewer for this supplement. Would it be possible to send us a paper copy of the following material. Please call me today.

Thanks,

Kalyani

A. Cover letter

B. Application Text

Item 1. TOC

Item 2. Labeling Section

Labeling History pp 1-2

Proposed Labeling pp 1-17

Item 3. Summary Section pp 1-138

Item 8. Clinical Section

Background and Overview pp 1-71

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Integrated Summary of Safety pp 1-272

Integrated Summary of Risks and Benefits pp 1-9

013 pp 1-95

025c pp 1-488

033c pp 1-581

034c pp 1-586

036c pp 1-233

037c pp 1-122

**APPEARS THIS WAY
ON ORIGINAL**

Bhatt, Kalyani

From: Rumbaugh_Trudy [Rumbaugh_Trudy@Allergan.com]
Sent: Tuesday, August 28, 2001 12:33 PM
To: 'Ko, Hon Sum'; Bhatt, Kalyani
Cc: Walton_Thomas
Subject: RE: FDA Request forData

I will have Thomas send this into the file officially upon his return from holiday (after 4 September). Is that timing okay with you, Kalyani? Kind regards, Trudy

-----Original Message-----

From: Ko, Hon Sum [mailto:KOH@cder.fda.gov]
Sent: Tuesday, August 28, 2001 2:56 AM
To: 'Rumbaugh_Trudy'
Cc: Walton_Thomas; Bhatt, Kalyani
Subject: RE: FDA Request forData

Trudy:
Thank you very much.
Please also send this in to the official file.
Best regards to you.
Hon-Sum.

-----Original Message-----

From: Rumbaugh_Trudy [mailto:Rumbaugh_Trudy@Allergan.com]
Sent: Monday, August 27, 2001 9:28 PM
To: 'Ko, Hon Sum'
Cc: Walton_Thomas
Subject: FW: FDA Request forData

Dear Dr. Ko,
Below I believe you will find the answer to your request which is documented in the email below this response. Please let me know if you need anything further while Thomas is on vacation until 4 September.

Kind regards, Trudy Rumbaugh

The histological parameters as well as a description of how the biopsies were to be handled were approved at Allergan in September, 2000 (please see attached document below):

<<190168-0.pdf>>

The histological slides were forwarded to an outside dermatopathologist [redacted] for evaluation (in a blinded manner) in December, 2000.

The dermatopathologist's evaluation was forwarded to Allergan in late December, 2000.

The statistical analysis plan was signed off January 12, 2001, before randomization was broken

The randomization code was broken on January 15, 2001

Statistical tables were available on January 24, 2001

-----Original Message-----
From: Walton_Thomas
Sent: Wednesday, August 22, 2001 10:48 AM
To: Sefton_John; Walker_Patricia
Cc: Rumbaugh_Trudy
Subject: FDA Request forData

FDA (Dr. Hon Sum Ko), has made a request that we supply FDA with information on the delineation of parameter for the histology study:

b) the location of references to the pertinent IND submissions
> regarding a priori delineation of parameters for histologic evaluation in meeting).
> Study -036C (as requested in pre-NDA meeting).

Thank you, Tom

"WorldSecure Server <cder.fda.gov>" made the following annotations on 08/27/01 21:24:51

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[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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"IRAPPS34 <allergan.com>" made the following annotations on 08/28/01 03:00:19

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[INFO] -- Access Manager:
This message was sent from FDA across the Internet in Encrypted format and was successfully decrypted unless otherwise noted.

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"WorldSecure Server <cder.fda.gov>" made the following annotations on 08/28/01 12:30:00

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted format and was successfully decrypted, unless otherwise noted.

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=====

Bhatt, Kalyani

From: Ko, Hon Sum
Sent: Tuesday, August 28, 2001 5:56 AM
To: 'Rumbaugh_Trudy'
Cc: Walton_Thomas; Bhatt, Kalyani
Subject: RE: FDA Request forData

Trudy:
Thank you very much.
Please also send this in to the official file.
Best regards to you.
Hon-Sum.

-----Original Message-----
From: Rumbaugh_Trudy [mailto:Rumbaugh_Trudy@Allergan.com]
Sent: Monday, August 27, 2001 9:28 PM
To: 'Ko, Hon Sum'
Cc: Walton_Thomas
Subject: FW: FDA Request forData

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<<190168-0.pdf>>

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The dermatopathologist's evaluation was forwarded to Allergan in late December, 2000.

The statistical analysis plan was signed off January 12, 2001, before randomization was broken

The randomization code was broken on January 15, 2001

Statistical tables were available on January 24, 2001

-----Original Message-----
From: Walton_Thomas
Sent: Wednesday, August 22, 2001 10:48
To: Sefton_John; Walker_Patricia
Cc: Rumbaugh_Trudy
Subject: FDA Request forData

FDA (Dr. Hon Sum Ko), has made a request that we supply FDA with information on the delineation of parameter for

ie
histology study:

b) the location of references to the
pertinent IND submissions
> regarding a priori delineation of
parameters for histologic evaluation in
> Study -036C (as requested in pre-NDA
meeting).

Thank you, Tom

"WorldSecure Server <cder.fda.gov>" made the following
annotations on 08/27/01 21:24:51

[INFO] -- Access Manager:
This message was sent from Allergan across the internet in encrypted
format and was successfully decrypted, unless otherwise noted.

=====
=====

Bhatt, Kalyani

From: Ko, Hon Sum
Sent: Wednesday, August 22, 2001 6:13 AM
To: 'Walton_Thomas'
Cc: Bhatt, Kalyani
Subject: NDA 21-184 S002

Sensitivity: Confidential

Tom:
Kalyani gave me the CD you made.
Thank you very much.
Hon-Sum.

Bhatt, Kalyani

From: Ko, Hon Sum
Sent: Friday, August 10, 2001 2:16 PM
To: 'Walton_Thomas'
Cc: Bhatt, Kalyani; Kozma-Fornaro, Mary J; Walker, Susan J
Subject: RE: NDA 21-184 S002

Tom:

Thank you for your email. I look forward to seeing the information on Study -036C. Some clarification is necessary on the other issues:

1. We are asking for review aids to facilitate the review. This is not to imply that you are deficient in the electronic submission. In the Guidance for Electronic Submission (P.6, under "Review Aids") is the following:

"Review aids are electronic files provided in addition to those provided for archive as described in the guidance. Like the review copy of an application, a review aid would contain only the information found in the archival copy of the application, but in a different format.

"Provide all review aid files on floppy disks or CDROMs and secure them in a standard binder marked clearly on the outside REVIEW AIDS - NOT FOR ARCHIVE. Include the review aids in the appropriate technical section of the review copy.

"In CDER, procedures have been established for identifying and requesting potential review aids to ensure that the quality and usefulness of the review aid is worth the time and effort invested in its development. Therefore, a review aid should only be requested or agreed to if (1) it will add functionality not found in a submission provided in accordance with guidance and (2) we agree that the review aid will contribute significantly to the review of the application."

Like the draft label, which you supplied as a review aid, those items in word processing format that I requested will also add functionality not found in the electronic archival copy, and certainly will contribute significantly to the review of the application.

Since your pdf files were probably created from word processing files, I don't think it is a hardship to supply the original word processing files to help the review.

2. We did not come to agreement on the timing of your open-label data submission. The minutes state:

"Information recommended by ICH E1A guideline should be submitted at the time of filing of the NDA. Material submitted at the time of filing would form the basis of the action on the application. Depending on the time of closure of the reviews, late information may or may not be included in labeling."

It is to your advantage to have them in as early as possible. Of course it is your call.

I hope you have a nice weekend.

Hon-Sum.

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, August 10, 2001 1:31 PM
To: 'Bhatt, Kalyani'; 'Ko_Hon Sum (FDA)'
Cc: Rumbaugh_Trudy
Subject: RE: NDA 21-184 S002

Dr. Ko:

I just spoke with Kalyani and she suggested I send you an e-mail.

The studies and the integrated summaries you requested are already available

electronically. Acrobat software allows cutting and pasting. We worked closely with Dr. Levine to ensure our electronic submission met FDA standards. If we have come up short somehow, please let me know.

The data for the on-going safety phase of the -033C study will be submitted at the 120-Day Safety Update, as per the agreement at the preNDA Meeting (submission -end of November). We will also be updating the ISS, the labeling and also sending in any relevant CRFs.

Lastly, I will work with our clinical group to obtain the data you requested for the parameters for the histology study (190168-036C). I don't think there is anything in the IND except the protocol, 1572, and investigator qualifications for the study. I will submit Allergan's rationale for the study parameters to the IND with a desk copy to you. Several clinical people are on vacation next week, so it might be a week or so before the information can be sent to you.

Please let me know if you have any comments or suggestions to Allergan's understanding of FDA's requirements.

Thank you, Dr. Ko.

Sincerely,

Tom Walton
Allergan

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Tuesday, August 07, 2001 5:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

-----Original Message-----

From: Bhatt, Kalyani
Sent: Monday, August 06, 2001 4:53 PM
To: 'tom_walton@allergan.com'
Subject: FW: NDA 21-184 S002

Tom, could you take care of this please.
Kalyani

> -----Original Message-----

> From: Ko, Hon Sum
> Sent: Friday, August 03, 2001 4:02 PM
> To: Bhatt, Kalyani
> Cc: Walker, Susan J
> Subject: NDA 21-184 S002

>

> Kalyani:

>

- > 1. The clinical needs are primarily for word-processing review aids:
 - > Clinical study reports for -025C, -033C, -034C, -036C and -037C;
 - > and the integrated summaries of effectiveness, safety, and risks/benefits.
- > 2. We also need to remind Allergan to supply
 - > a) the 28-week open-label data of study 033C as soon as possible,
 - > and
 - > b) the location of references to the pertinent IND submissions
- > regarding a priori delineation of parameters for histologic evaluation in
- > Study -036C (as requested in pre-NDA meeting).

Thank you.

> Hon-Sum.

>

"IRAPPS34 <allergan.com>" made the following annotations on 08/06/01 13:56:55

[INFO] -- Access Manager:

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"IRAPPS34 <allergan.com>" made the following annotations on 08/07/01 05:26:32

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"WorldSecure Server <cder.fda.gov>" made the following annotations on 08/10/01 13:28:01

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Friday, August 10, 2001 1:31 PM
To: 'Bhatt, Kalyani'; 'Ko_Hon Sum (FDA)'
Cc: Rumbaugh_Trudy
Subject: RE: NDA 21-184 S002

Hi Dr. Ko:

I just spoke with Kalyani and she suggested I send you an e-mail.

The studies and the integrated summaries you requested are already available electronically. Acrobat software allows cutting and pasting. We worked closely with Dr. Levine to ensure our electronic submission met FDA standards. If we have come up short somehow, please let me know.

The data for the on-going safety phase of the -033C study will be submitted at the 120-Day Safety Update, as per the agreement at the preNDA Meeting (submission -end of November). We will also be updating the ISS, the labeling and also sending in any relevant CRFs.

Lastly, I will work with our clinical group to obtain the data you requested for the parameters for the histology study (190168-036C). I don't think there is anything in the IND except the protocol, 1572, and investigator qualifications for the study. I will submit Allergan's rationale for the study parameters to the IND with a desk copy to you. Several clinical people are on vacation next week, so it might be a week or so before the information can be sent to you.

Please let me know if you have any comments or suggestions to Allergan's understanding of FDA's requirements.

Thank you, Dr. Ko.

Sincerely,

Tom Walton
Allergan

-----Original Message-----

From: Bhatt, Kalyani [mailto:BHATTK@cderr.fda.gov]
Sent: Tuesday, August 07, 2001 5:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

-----Original Message-----

From: Bhatt, Kalyani
Sent: Monday, August 06, 2001 4:53 PM
To: 'tom_walton@allergan.com'
Subject: FW: NDA 21-184 S002

Tom, could you take care of this please.
Kalyani

> -----Original Message-----
> **From:** Ko, Hon Sum

Sent: Friday, August 03, 2001 4:02 PM
To: Bhatt, Kalyani
> Cc: Walker, Susan J
> Subject: NDA 21-184 S002
>
> Kalyani:
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> 1. The clinical needs are primarily for word-processing review aids:
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> and the integrated summaries of effectiveness, safety, and
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Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Tuesday, August 07, 2001 6:35 PM
To: 'Rumbaugh_Trudy'
Subject: RE: NDA 21-184 S002

Importance: High

Thanks Trudy I appreciate it. K

-----Original Message-----

From: Rumbaugh_Trudy [mailto:Rumbaugh_Trudy@Allergan.com]
Sent: Tuesday, August 07, 2001 5:34 PM
To: 'Bhatt, Kalyani'
Cc: Walton_Thomas
Subject: RE: NDA 21-184 S002

Will do Kalyani. Although Tom is back in the office tomorrow and will probably be handling the bulk of this regardless. -Trudy

Trudy Rumbaugh, MD
Director, Global Regulatory Affairs, Retinoids
ph 714-246-4292 fax -4272

---Original Message---

From: Bhatt, Kalyani [mailto:BHATTK@cder.fda.gov]
Sent: Tuesday, August 07, 2001 5:39 AM
To: 'rumbaugh_trudy@allergan.com'
Subject: FW: NDA 21-184 S002

Hi Trudy,
I know Tom is out of the office could you please make sure that the agency receives the following material.
Kalyani

-----Original Message-----

From: Bhatt, Kalyani
Sent: Tuesday, August 07, 2001 8:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

-----Original Message-----

From: Bhatt, Kalyani
Sent: Monday, August 06, 2001 4:53 PM
To: 'tom_walton@allergan.com'
Subject: FW: NDA 21-184 S002

Tom, could you take care of this please.
Kalyani

> -----Original Message-----

> **From:** Ko, Hon Sum
> **Sent:** Friday, August 03, 2001 4:02 PM
> **To:** Bhatt, Kalyani

Cc: Walker, Susan J
Subject: NDA 21-184 S002

>
> Kalyani:
>
> 1. The clinical needs are primarily for word-processing review aids:
> Clinical study reports for -025C, -033C, -034C, -036C and -037C;

> and the integrated summaries of effectiveness, safety, and
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in
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"IRAPPS34 <allergan.com>" made the following
annotations on 08/07/01 05:44:52

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"WorldSecure Server <cder.fda.gov>" made the following
annotations on 08/07/01 17:30:11

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format and was successfully decrypted, unless otherwise noted.

Bhatt, Kalyani

From: Rumbaugh_Trudy [Rumbaugh_Trudy@Allergan.com]
Sent: Tuesday, August 07, 2001 5:34 PM
To: 'Bhatt, Kalyani'
Cc: Walton_Thomas
Subject: RE: NDA 21-184 S002

Will do Kalyani. Although Tom is back in the office tomorrow and will probably be handling the bulk of this regardless. -Trudy

Trudy Rumbaugh, MD
Director, Global Regulatory Affairs, Retinoids
ph 714-246-4292 fax -4272

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To: 'rumbaugh_trudy@allergan.com'
Subject: FW: NDA 21-184 S002

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I know Tom is out of the office could you please make sure that the agency receives the following material.
Kalyani

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From: Bhatt, Kalyani
Sent: Tuesday, August 07, 2001 8:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

-----Original Message-----
From: Bhatt, Kalyani
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To: 'tom_walton@allergan.com'
Subject: FW: NDA 21-184 S002

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Kalyani

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> From: Ko, Hon Sum
> Sent: Friday, August 03, 2001 4:02 PM
> To: Bhatt, Kalyani
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> Subject: NDA 21-184 S002
>

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[INFO] -- Access Manager:
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Bhatt, Kalyani

From: Timmer, William C
Sent: Tuesday, August 07, 2001 12:25 PM
To: 'Walton_Thomas'
Cc: 'rumbaugh_trudy@allergan.com'; Bhatt, Kalyani
Subject: RE: Removal of [redacted] Supplier from NDAs 20-600 and 21-184

Tom:

Unfortunately for you (or maybe fortunately for you), I will no longer be reviewing Allergan's submissions in the Division of Derm and Dental. I have moved over to the Div of Oncology. It is a lateral move, but it does have some advantages for me. (Among other, it's closer to home, and closer to the NIH, where I have a part-time research project).

I've enjoyed working with you, and Trudy, these last few years. I'm sure we will be hearing about each other in the future.

Best wishes to you, Trudy, and the rest of the Allergan team.

Bill Timmer

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, July 27, 2001 1:24 PM
To: 'Bhatt, Kalyani (e-mail)'; 'Timmer_William, FDA'; Cross_Frank FDA
Cc: Rumbaugh_Trudy; Quigg_Jeanne
Subject: Removal of [redacted] Supplier from NDAs 20-600 and 21-184

Dear Ms Bhatt, Mr. Cross and Dr. Timmer:

Allergan is removing [redacted]
as a
supplier of [redacted] all Tazarotene-containing products. [redacted]

[redacted]

We will be supplementing the above NDAs shortly and cross referencing the many INDS that are open for both topical and oral formulations of tazarotene.

The remaining supplier of tazarotene is [redacted] was inspected last year by FDA.

I am sending you this as NDA 21-184 has S-001 and S-002 open and in case you had planned an inspection of [redacted]

You should receive the supplements next week. Please let me know if you have any questions.

"WorldSecure Server <cder.fda.gov>" made the following annotations on 07/27/01 13:19:59

[INFO] -- Access Manager:

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ormat and was successfully decrypted, unless otherwise noted.

=====

APPEARS THIS WAY
ON ORIGINAL

Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Tuesday, August 07, 2001 8:39 AM
To: 'rumbaugh_trudy@allergan.com'
Subject: FW: NDA 21-184 S002

Hi Trudy,
I know Tom is out of the office could you please make sure that the agency receives the following material.
Kalyani

-----Original Message-----
From: Bhatt, Kalyani
Sent: Tuesday, August 07, 2001 8:22 AM
To: 'walton_thomas@allergan.com'
Subject: FW: NDA 21-184 S002

-----Original Message-----
From: Bhatt, Kalyani
Sent: Monday, August 06, 2001 4:53 PM
To: 'tom_walton@allergan.com'
Subject: FW: NDA 21-184 S002

Tom, could you take care of this please.
Kalyani

> -----Original Message-----
> **From:** Ko, Hon Sum
> **Sent:** Friday, August 03, 2001 4:02 PM
> **To:** Bhatt, Kalyani
> **Cc:** Walker, Susan J
> **Subject:** NDA 21-184 S002
>
> Kalyani:
>
> 1. The clinical needs are primarily for word-processing review aids:
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> and the integrated summaries of effectiveness, safety, and
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> 2. We also need to remind Allergan to supply
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==

APPEARS THIS WAY
ON ORIGINAL

Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Tuesday, August 07, 2001 8:24 AM
To: Bhatt, Kalyani
Subject: Out of Office AutoReply: NDA 21-184 S002

I will be out of the office returning Wednesday, August 8. In the interim, please contact Trudy Rumbaugh at 714.246.4292.

"WorldSecure Server <cder.fda.gov>" made the following annotations on 08/07/01 08:20:19

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APPEARS THIS WAY
ON ORIGINAL

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From: Bhatt, Kalyani
Sent: Tuesday, August 07, 2001 8:22 AM
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> **From:** Ko, Hon Sum
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> **To:** Bhatt, Kalyani
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> **Subject:** NDA 21-184 S002

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Kalyani:

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Bhatt, Kalyani

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Subject: FW: NDA 21-184 S002

Tom, could you take care of this please.
Kalyani

-----Original Message-----

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Sent: Friday, August 03, 2001 4:02 PM
To: Bhatt, Kalyani
Cc: Walker, Susan J
Subject: NDA 21-184 S002

Kalyani:

1. The clinical needs are primarily for word-processing review aids:
Clinical study reports for -025C, -033C, -034C, -036C and -037C;
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 - a) the 28-week open-label data of study 033C as soon as possible, and
 - b) the location of references to the pertinent IND submissions regarding a priori delineation of parameters for histologic evaluation in Study -036C (as requested in pre-NDA meeting).

Thank you.

Hon-Sum.

Bhatt, Kalyani

From: Bhatt, Kalyani
Sent: Friday, July 27, 2001 1:46 PM
To: 'Walton_Thomas'
Subject: RE: Removal of [redacted] Supplier from NDAs 20-600 and 21-184

Importance: High

Thanks Tom for the update.
Kalyani

-----Original Message-----

From: Walton_Thomas [mailto:Walton_Thomas@Allergan.com]
Sent: Friday, July 27, 2001 1:24 PM
To: 'Bhatt, Kalyani (e-mail)'; 'Timmer_William, FDA'; Cross_Frank FDA
Cc: Rumbaugh_Trudy; Quigg_Jeanne
Subject: Removal of [redacted] Supplier from NDAs 20-600 and 21-184

Dear Ms Bhatt, Mr. Cross and Dr. Timmer:

Allergan is removing [redacted]
as a
supplier of [redacted] all Tazarotene-containing products. [redacted]

[redacted]

We will be supplementing the above NDAs shortly and cross referencing the many INDs that are open for both topical and oral formulations of tazarotene.

The remaining supplier of tazarotene is [redacted] was inspected last year by FDA.

I am sending you this as NDA 21-184 has S-001 and S-002 open and in case you had planned an inspection of [redacted]

You should receive the supplements next week. Please let me know if you have any questions.

"WorldSecure Server <cdcr.fda.gov>" made the following annotations on 07/27/01 13:19:59

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Bhatt, Kalyani

From: Walton_Thomas [Walton_Thomas@Allergan.com]
Sent: Friday, July 27, 2001 1:24 PM
To: 'Bhatt, Kalyani (e-mail)'; 'Timmer_William, FDA'; Cross_Frank FDA
Cc: Rumbaugh_Trudy; Quigg_Jeanne
Subject: Removal of [redacted] Supplier from NDAs 20-600 and 21-184

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Allergan is removing [redacted]
as a
supplier of [redacted] all Tazarotene-containing products. [redacted]
has [redacted]
[redacted]

We will be supplementing the above NDAs shortly and cross referencing
the
many INDs that are open for both topical and oral formulations of
tazarotene.

The remaining supplier of tazarotene is [redacted] [redacted] was
inspected last year by FDA.

I am sending you this as NDA 21-184 has S-001 and S-002 open and in case
[redacted] planned an inspection of [redacted]

You should receive the supplements next week. Please let me know if you
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ALLERGAN INC.
REGULATORY AFFAIRS
 2525 Dupont Drive
 Irvine, California 92612

FAX COVER SHEET

TO: Ms. Kalyoni Brett FROM: Peter Kresel
FDA
 FAX: 301/827-2075 FAX: (714) 246-4272
 TELEPHONE: _____ TELEPHONE: (714) 246-6781

 CC: _____ DATE: 9-26-02

 Pages being sent including this cover page: 2

Message:

If you do not receive entire document, please call: 714/246-6552

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ALLERGAN



2525 Dupont Drive, P.O. Box 19534, Irvine, California, USA 92623-9534 Telephone: (714) 246-4500 Website: www.allergan.com

September 26, 2002

Ms. Kalyani Bhatt
Regulatory Health Project Manager
Division of Dermatological and Dental Drug Products
HFD-540/Room N241
Food and Drug Administration
Center for Drug Evaluation and Research
9201 Corporate Boulevard, Building 2
Rockville, MD 20850

**REF: Photo Damage Cream
(NDA 21-184/S-002)**

Dear Ms. Bhatt:

As follow-up to the conversation held September 25, 2002 between you and Dr. DeCamp of the Agency and Dave Garbe and Peter Kresel representing Allergan, Allergan agrees to revise the Avage carton and label per Dr. DeCamp's request.

Sincerely,

Peter A. Kresel
Senior Vice President
Global Regulatory Affairs

PAK/lm