

Lemley, Lee

39

From: Bechtel, Christine
Sent: Tuesday, April 09, 2002 4:23 PM
To: Lemley, Lee
Cc: Roberts, Khyati N
Subject: RE: accutane questions

Lee,
Both Julie Beitz and Anne Trontell still agree with the 1 in 100 number for question #6. (I had Kathleen check with them and they are on the email string below as saying this.)

That is, Question 6. Does the FDA have any estimate about what percentage of adverse effects are actually reported to the FDA?

Chris

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

From: Lemley, Lee
Sent: Tuesday, April 09, 2002 12:22 PM
To: Bechtel, Christine; Roberts, Khyati N
Subject: FW: accutane questions

FYI - Verifying numbers reported by press office. I was not aware of the article but press must have contacted ODS to get them??

Lee

Lee Lemley
Policy Analyst
Executive Operations Staff
Office of Executive Programs
(301) 594-6218

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

From: Rumble, Terri F
Sent: Tuesday, April 09, 2002 12:05 PM
To: Lemley, Lee
Subject: FW: accutane questions

fyi

Terri

Terri F. Rumble
Associate Director of Regulatory Affairs
Office of Drug Evaluation V
Center for Drug Evaluation and Research
301-827-2268 phone
301-827-2317 fax

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

From: Kolar, Kathleen M
Sent: Tuesday, April 09, 2002 12:02 PM
To: Trontell, Anne E; Beitz, Julie G; Wilkin, Jonathan K
Cc: Kozma-Fornaro, Mary J; Rumble, Terri F; Bull, Jonca; O Connell, Kathryn A; Aaron, Leslyn
Subject: RE: accutane questions

Hello all. Just wanted to let you know an article on the Accutane S.M.A.R.T. program is in today's Washington Post Health Section. It is also listed in our clips if you need to electronically pull it up.

I actually have a clarification question for either Ann or Julie. In the article I am quoted as saying "Only about one in 10 adverse drug effects are reported to the FDA and agency spokesperson Kathleen Kolar says that figure could be as low as one in 100." I do not exactly remember quoting the 1 in 100 figure but would that be accurate going with the information we have?

KK

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

From: Trontell, Anne E
Sent: Thursday, March 21, 2002 2:15 PM
To: Beitz, Julie G; Wilkin, Jonathan K; Kolar, Kathleen M
Cc: Kozma-Fornaro, Mary J; Rumble, Terri F; Bull, Jonca
Subject: RE: accutane questions

"As low as 1%" is a good figure to quote.

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

From: Beitz, Julie G
Sent: Thursday, March 21, 2002 1:03 PM
To: Wilkin, Jonathan K; Kolar, Kathleen M
Cc: Trontell, Anne E; Kozma-Fornaro, Mary J; Rumble, Terri F; Bull, Jonca
Subject: RE: accutane questions

Jon and Kathleen,

I'll forward this to Marilyn, as we may have updated numbers now for item #5. We've used various estimates for the fraction of adverse event reports that are actually received. I use "as low as 1%". Anne may suggest another figure.

Julie

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

From: Wilkin, Jonathan K
Sent: Thursday, March 21, 2002 12:42 PM
To: Kolar, Kathleen M
Cc: Trontell, Anne E; Beitz, Julie G; Kozma-Fornaro, Mary J; Rumble, Terri F; Bull, Jonca
Subject: RE: accutane questions

Kathleen,

...and the answers are:

1. Nothing beyond the labeling, i.e., no special pregnancy prevention program separate from warnings in labeling existed.
2. No, there are no other drugs.
3. If they don't comply, then the current risk management program will not be found to be a success, and a more rigorous program may be instituted.
4. Roche would know.
5. & .6 Anne Trontell or Julie Beitz would be the best sources for these answers.

Thanks,
Jon

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

From: Kolar, Kathleen M
Sent: Thursday, March 21, 2002 10:37 AM
To: Wilkin, Jonathan K
Subject: FW: accutane questions

Apparently you spoke to this reporter for the Washington Post, with Rae, a few months back. She has a few additional questions since her article was put on hold to be closer to the 4/10 program deadline. Would you be able to talk with her again tomorrow sometime between 10 and 5 or today between 4 and 5? I can get an answer to number 5 from ODS.

Let me know.
Kathleen Kolar

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

From: Diane Knich [mailto:knichd@washpost.com]
Sent: Thursday, March 21, 2002 10:25 AM
To: Kolar, Kathleen M
Subject: Re: accutane questions

I'm not sure this went through so I'm sending it again.

Diane

Ms. Kolar:

Thank you for getting back to me. I hope the E-mail that included the times that I am available was sent to you. Call me if it wasn't. Here are my questions for Dr. Wilkin. Please call me as soon as possible with a time that he is available.

Thanks,

Diane Knich

202-334-5031

MY QUESTIONS

1. There has been a pregnancy prevention program since 1988, what was happening before 1988? What was going on between 1982 and 1988?
2. Are there any other drugs that use a system like the SMART program?
That is, the collaboration between manufacturer, doctor and pharmacist? That use stickers like the new ones necessary to obtain Accutane? Is this system a first?
3. What are the consequences if a doctor or pharmacist doesn't comply?
4. What has the response been like to the program and to the letters sent out in January? (or is that a question for Roche?)
5. Are the following figures correct? Between the time the drug was introduced in 1982 and June 30, 2001, 2,181 pregnancies have been reported to the FDA. This number includes 1,310 elective abortions, 242 spontaneous abortions, 192 normal babies and 166 babies born with birth defects.
6. Does the FDA have any estimate about what percentage of adverse effects are actually reported to the FDA?

"Kolar, Kathleen

M"

<KKOLAR@OC.FDA.GO

V>

To: "'knichd@washpost.com'" <knichd@washpost.com>

cc:

Subject: accutane questions

03/21/2002 09:18
AM

Diane,

Hello. I am actually handling Accutane now. Rae is the back up on the issue. Why don't you go ahead and send me your questions and I'll pass them along to Dr. Wilkin and try to schedule something.

Kathleen Kolar