

Om
AG
① 1/8/87
2/18/87

To: Frank / Jan

From: RT

Subject: Falpat

The standard on Falpat is on hold pending resolution of the following (Jan add to list if I missed something)

1. Compare risk reduction measures in capten, captatal, falpat standards. What required in each? Why? IA differences, why? Should Falpat or other standards be changed?

John

2. Artg has identified 4 places in std and fact sheet where we imply future special review (i.e., "we will consider other reg. options...") Take it out

DONE ✓

DONE ✓

3. Applicator Exposure data requirements need to be added - "Table C" explain in narrative? "TABLE A"

36 mo.

24 mo.

4. Residue/metabolism deadlines were screened by Jan can explain

done.

5. Re: ^{rat} once data requirements -

What are we asking for? Get HED concurrence. If it is only historical control data get it in 3 months. How do we get it? - take std? letter?

Steve S

3/10

6. Re: Terata - we need to

get backup data on hamster study. Who & How? we need to contact unknown person at Dartmouth? for control data Cpts at work on hamsters. Who / How

Steve S

7. Re: ^{rat} Alpha - what are we

asking for? Get HED concurrence. If it is only

historical data, same as 5 above. For 5 + 2

if we want hist. data

& then may ask for repeat studies, pat. studies

in standard & "Reserve"

than pending review of

hist. data

Steve S

WHO -> Priya will call ->

8. We need OTS structure

activity call on folypat/control

penetration & perhaps health effects (?)

9) Based on resolution of the above, we can revise standard but risk reduction measures will require Jans/Jack etc & will need valid reason for the measures.

10) I would like each of you to give this your personal attention - Jan to ensure JRS's needs are met in the standard and Frank to get standard into shape

✓ 11) I will schedule meeting 2/27 to discuss status

12) I apologize for hassle but we might as well get it right

13) Please get together to discuss