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Waugh, Joanna {PDR~Nutley}

From: Dinella, Cynthia {Deve~Nutley}
sent: Tuesday, October 30, 2001 5:33 PM
To: Reilly, Tammy {Derm~Nutley}; Fox, Michael {Derm~Nutley}; Manfredi, Louis E {Derm~Nutley}; Leach, Eileen {Derm~Nutley}; Gemayel, Georges {Phar~Nutley}; Kentz, Frederick {CORP~Nutley}; McMurray, Julie L. {GENE~Nutley}; Mathews, Jane {LAW~Nutley}; Glynn, Carolyn {CORP~Nutley}; Eging, Michael J {PUBL~Nutley}; Sandor, David W {PUBL~Nutley}; Safian, Gail {PUBL~Nutley}; Burns, Brian {FEDE~Nutley}; Abercrombie, George {CORP~Nutley}; Haasner, Dirk {PBH~Basel}; Kenny, Daniel {PBH~Basel}; Kalb, Alexandra {PDR~Basel}; Frederick, Anne {PDR~Nutley}; Waugh, Joanna {PDR~Nutley}; Zabrowski, Daniel L {Deve~Nutley}; Barr, Richard {PDR~Nutley}; Ackermann, Susan Patricia {DRUG~Nutley}; LaFlore, John {Deve~Nutley}; Huber, Martin Harold {PDC6~Basel}; Raff, Sandra {DRUG~Nutley}; Bess, Kathryn {DRUG~Nutley}; Ellison, Russell {Phar~Nutley}
Subject: FW: NDA 18-662 Accutane SLR-044 Action Letter and Labels.



NDA 18-662 Accutane
SLR-044 e...

Dear All -

Please find enclosed the final approval letter with all approved components of the enhanced pregnancy program, S.M.A.R.T. There are no big surprises as per our discussions over the last days and months. Therefore, they have agreed to the metrics, the timing and the components of the program as Roche proposed.

There are a few items that we will need to follow-up on as per the approval letter. However, I do not want anyone distracted over this letter in light of the PK supplement and Risk Management letter to be sent on Friday or Monday latest. Therefore, we will not convene meetings to discuss content of this letter this week because Regulatory does not believe any of the items deserve immediate attention.

Please try to CELEBRATE the following:

- (1) No registry which was the strategic direction given to us one year ago and would have alienated our primary stakeholder (AAD) and would have had confidentiality issues.
- (2) No Advisory Committee prior to getting this approved - big success here!!
- (3) Success with getting physician education into the label.
- (4) Father exposed and depression removed from proposed black box to be placed in the precaution section.
- (5) Incredible success with the metrics and timing - June 2003 (unbelievable!!).

Personally I would like to thank everyone who suffered through monthly challenging FDA meetings and putting in an amazing amount of work while dealing with so many different views and issues. The outcome could have been drastically different. It was your efforts and the guidance of the Steering Committee that kept us ahead by one step! I would like to acknowledge (not in any order) the following: Eileen, Mike, Tammy, Russell, Susan, Winslow, John, Sandi, Kay, Julie (and Bruce), David, Gail, Dirk, Joanna and Anne.

Have a nice night!
cindy

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

From: Waugh, Joanna {PDR~Nutley}
Sent: Tuesday, October 30, 2001 4:47 PM
To: Dinella, Cynthia {Deve~Nutley}
Subject: FW: NDA 18-662 Accutane SLR-044 Action Letter and Labels.