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Tuesday, November 11, 2003 2:56:40 PM

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Subject:

Wednesday Cough/Cold Meeting

Attachments: Projects2.xls

In place of the Wednesday Cough/Cold meeting this week, we will meet to discuss ongoing and proposed projects, resources, and timing in preparation for the FY 2005 budget. Please review the attached list of projects and come to the meeting prepared to identify specific activities performed by you and your reports to support and/or execute each project. At this initial meeting we will focus on providing task details and timing required to complete projects that require 2 or more FTEs and identifying individuals needed for each task. Note that the MX projects are included in the list to serve as "markers" until substitute products are identified.

PLAINTIFFS'
TRIAL EXHIBIT
PTX0255

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Product and Process Development Projects

Priority	Project
1	Astelin - Qualify O-B 5502BN Bottle Resin
1	Astelin - Feasibility Study - V Bottom/Pump Placer
1	Astelin - Evaluate NCO8 Pump Actuator
1	Astelin - Nasal Spray Reformulation
1	Qualify Alternate Astelin NS Manufacturing and Testing Site
1	Tussi-12D Suspension - Commitments to Compliance
1	Update Tannate Drug Substance Assay - JFC Methods
1	Preformulation Evaluation of Tannate Actives
1	Sina-12X - Monitor Stability Programs
1	Ryna-12X - Monitor Stability Programs
1	Tussi-12X Suspension - Develop Formulation & Methods
11	Tussi-12X Tablets - Develop Formulation & Methods
1	Packaging Evaluation for Tannate Products
1	Doral Tablets - Dissolution Profile Testing and Evaluation
1	Depen - Qualify Manufacturing Site
1	Optivar - Manufacturing Process Transfer Support
1	Depen/Soma - Degradation Evaluation
11	Astelin - Maintain Commercial Supply
11	EZ Chrome Computer Validation (21 CFR 11)
11	Cranbury GMP Compliant Operational Procedures (SOPs)
1	Cranbury GMP Compliant Set-Up IQ/OQ/PQ Lab Equipment
1	Cranbury GMP Compliant Training
11	Astelin - Sample Package Fill Optimization
1	Astelin - Qualify Calmar-Albert Pump
11	Astelin - Transfer Extractables Method to Valois
2	Quality - Support Site Audits
2	Intellectual Property/Due Diligence/Tech Eval/Licensing
2	Reference Standards Program
2	Soma Sustained Release - Develop Formulation
2	Modernize Decatur Analytical Methods
2	Drug Substance Optimization
2	Analytical Site Change Submission for Transferred Products
2	Astelin - Full Pump Release Testing at Valois
2	Astelin - Full Pump Release Testing at Calmar
2	Decrease Phenylephrine Tannate Overage
2	Anti-oxidant for Cough/Cold Products
2	Optivar - Smaller Sample Size

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2	Astelin - Justify Removal of Nitrosamine Specification for Pump
2	Soma 350 - Qualify Alternate Manufacturing Site
3	Sina-12 MX Suspension - Feasibility Evaluation
3	Sina-12 MX Tablets - Feasibility Evaluation
3	Sina-12 MX Suspension - Develop Formulation and Methods
3	Sina-12 MX Tablets - Develop Formulation and Methods
3	Sina-12 MX Tablets - Transfer Process and Methods
3	Sina-12 MX Suspension - Transfer Process and Method
3	Ryna-12 MX Suspension - Feasibility Evaluation
3	Ryna-12 MX Tablets - Feasibility Evaluation
3	Ryna-12 MX Tablets - Transfer Process and Methods
3	Ryna-12 MX Suspension - Transfer Process and Method
3	Ryna-12 MX Suspension - Develop Formulation & Methods FY05
3	Ryna-12 MX Tablets - Develop Formulation & Methods FY05
3	Fluorofelbamate - Develop for IND
3	Fluorofelbamate - Preformulation Evaluation
3	Fluorofelbamate - IND and Scale-Up Support
3	Doral Tablets - Qualify New Drug Substance Supplier
3	Fluorofelbamate - Develop And Evaluate Clinical Capsule Stability
3	Tussi-12X Backup Suspension - Develop Formulation & Methods
3	Tussi-12X Backup Tablets - Develop Formulation & Methods
3	Astelin-D (Decongestant) - Feasibility Evaluation
3	Soma - Lower Dose
3	Astelin - Qualify O-B Equistar Bottle Resin
3	Facility/Lab/Office Management
4	Doral Tablets - Intermediate Dose
4	Fluorofelbamate - Develop Tablet formulation
4	Fluorofelbamate - Develop Pediatric Formulation
4	Felbamate - Qualify Recrystallization (Orgamol)
4	Soma 350 - Develop/Validate New Deg Products Method
4	Astelin - Investigate Elimination of BAC Adjustment Step
4	Butisol - Validate Residual Acetone/ETAC Test Method
4	Astelin NS/Steroid Combo - Feasibility of Dual Chamber
5	Soma CC - Revise Current Dissolution Method
5	Soma CC- Develop/Validate New Deg Products Method
5	Support Marketing (e.g., color change)
5	Astelin - Develop Pediatric Product

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