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Subject: Life Cycle Management Astelin Projects
Attachments: Life Cycle Management Astelin Projects

Barabara: here's the LCM document for distribution. Thanks, Bill
Life Cycle Management Astelin Projects

ASTELIN® NASAL SPRAY

LIFE CYCLE MANAGEMENT PROJECTS

(Preliminary Plan)

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PACKAGING CONFIGURATION PROJECTS

Product: ASTELIN NASAL SPRAY

Project: Pediatric Packaging

Objective: To develop a new Astelin Nasal Spray packaging configuration that will be designated as "Pediatric" containing a single 17mL flat bottom bottle and a single current VP3 Valois pump.

Background: FDA approval has been obtained for the use of Astelin Nasal Spray in children 5 to 11 years of age. The current packaging configuration provides twice the product volume for pediatric patients, compared to adults (based on the differences in dose). Therefore, rather than 2 x 17mL bottles and one pump provided in an adult trade carton, one 17mL bottle and one pump will be provided in a pediatric trade carton. Development of this pediatric package involves labeling revisions to the following: package insert, patient instructions, 17mL bottle label, trade carton.

Feasibility: High

Likelihood of Success: High.

Time: There are three possible scenarios which would affect timing:
(1) Annual Reportable Change: internal revision of the product labeling to simply remove all references to two 17mL bottles and any artwork geared toward adults, making no reference to a "Pediatric Package". This change could be implemented as soon as final printed labeling (FPL) is available and would only require notification to FDA in the subsequent NDA Annual Report.
(2) Changes Being Effected (CBE) Supplement or Annual Reportable: internal revision of the labeling to remove all references to two 17mL bottles and include a reference to "Pediatric Package" and artwork geared toward children on the bottle and/or carton regarding "Pediatric Package". Depending upon the extent of the pediatric package marketing spin (to be evaluated by Regulatory), this change could either be handled as indicated in 1) above, or it would require the submission of a CBE. For the CBE, draft labeling would be submitted in a supplement which could be implemented after 30 days, unless FDA objected.
(3) CBE or Prior Approval Supplement (PAS): in addition to internal labeling changes to remove all references to two 17mL bottles, addition of artwork geared toward children and indication of "Pediatric Package", if a value added piece (to be evaluated by Regulatory) is to be included, submission of a CBE or PAS would be required. FDA approval (PAS) would be required in almost any case of the use of value added material.

Cost: A cost of approximately $1000.00 per individual piece of product labeling will be incurred. Total cost approximately $5000.00. Cost for destruction of existing label inventory TBD.

Milestones/Go no Go Decisions:

Milestone	Timing	Cost
Resolution of the issues concerning the Sepracor contract	TBD	TBD
Determination of the changes to be incorporated	TBD	TBD
Determination of short vs long-term use of pediatric package*	TBD	TBD
Determination of FDA submission requirements	BD	TBD
Initiation of internal approval process for labeling components	1-2 weeks	TBD
Completion of labeling approval process	2-3 weeks	TBD
Submission to FDA	TBD	TBD
Launch	TBD	TBD

Promotability: Labeling change could be used to support safety and convenience/cost savings in pediatric patients.

Market Forecast:

* Based upon recent market "models". Links into life cycle for V-bottom bottle configuration.

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