

ENCLOSURE B

PROPOSED LABELING CHANGES

Prednisolone Sodium Phosphate, USP, Oral Solution, 10mg prednisolone base/5mL

Changes are based on the current approved labeling for Pediapred,
prednisolone sodium phosphate, USP, oral solution

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1. In connection with product name, change “6.7mg/5mL” to “13.4mg/5mL.”
2. Change revision date and control number as appropriate.
3. In “Description,” revise “dye free, colorless to light straw colored, raspberry flavored” as appropriate to reflect the proposed product for which an ANDA will be filed. Revise next sentence to state: “Each 5mL (teaspoonful) contains 13.4mg prednisolone sodium phosphate (10mg prednisolone base) in a palatable, aqueous vehicle.”
4. Revise statement regarding product ingredients to correspond to composition of the proposed product for which an ANDA will be filed.

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5. In “How Supplied” statement, revise “colorless to light straw colored solution” to reflect the proposed product for which an ANDA will be filed. Revise remainder of sentence to read: “containing 13.4mg prednisolone sodium phosphate (10mg prednisolone base) per 5mL (teaspoonful).”

6. Revise NDC number as appropriate.

7. Revise "120mL bottle" as appropriate to reflect the container size(s) of the proposed product for which an ANDA will be filed.

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8. Revise identity of manufacturer, copyright statement, control number, and revision date as appropriate.

AYT:cr
2/09/06