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APPLICATION NUMBER:NDA 20236/S017

ADMINISTRATIVE DOCUMENTS

DEC 1 1 1998

Project Manager's Labeling Review

Project Manager: Parinda Jani
NDA: 20236/S-017
Product: Serevent Inhalation Aerosol
Sponsor: Glaxo Wellcome Inc
Submission Date: July 6, 1998

Date: December 11, 1998

Supplement S-017 provides for the changes to the PRECAUTIONS: Labor and Delivery section and OVERDOSAGE section. Also, "Rx only", patent and copyright statements have been added to the end of the labeling.

PRECAUTIONS: Labor and Delivery: The second sentence has been revised to "....use of SEREVENT Inhalation Aerosol for prevention of bronchospasm during labor should be restricted..."

OVERDOSAGE: The first sentence has been revised to "The expected signs and symptoms with overdosage...". Also, the sentence "Cardiac monitoring is recommended in cases of overdosage" has been added to the end of the third paragraph.

Also, "Rx only", patent and copyright statements have been added to the end of the labeling. There are no other changes made to the labeling.

Recommendation: Supplement S-017 should be approved. Dr. Meyer's review dated December 14, 1998, recommends approval of this supplement.

The sponsor will be informed to modify the efficacy tables in the Clinical Trials subsection of the CLINICAL PHARMACOLOGY section to include the precise Serevent product that is the source of the data, i.e., instead of just SEREVENT, it should specify Serevent Inhalation Aerosol (NDA 20-236) and Serevent Inhalation Powder (NDA 20-692). This change to the labeling should be made within 6 months, or at the next printing, whichever comes first.

/S/

Parinda Jani
Project Manager