

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-078 / S-001

CHEMISTRY REVIEW(S)

Labeling and Chemistry Review of Supplemental Labeling Revision (SLR):

Materials Reviewed:

Product	NDA #	SLR #	Letter Date	Receipt Date	Completed Date
Malarone™ (atovoquone and proguanil) Tablets	21-078	001	September 21, 2000	September 22, 2000	February 19, 2002

Sponsor: GlaxoSmithKline (formerly Glaxo Wellcome)

Background:

NDA 21-078 was originally approved on July 14, 2000. There have been no approved labeling changes since that time. There are currently two container labels approved for Malarone: one for adult tablets, and one for pediatric tablets.

On July 11, 2000 (prior to the NDA approval) the Division sent a fax to GlaxoSmithKline requesting that changes be made to the Malarone container labels. The Division was concerned that:

1. The strength designation should have more prominence, and the strength of each of the Malarone components should be highlighted.
2. The tablet count should be reduced in prominence so that there is no confusion with the tablet strength.

An internal Division meeting was held on December 5, 2001 to discuss the company's proposed container labels. David Cummings, Chemistry Reviewer and Dr. Norman Schmuff, Chemistry Team Leader determined that the Division's concerns regarding the original labels had been addressed and the new proposed labels were acceptable.

Conclusions/Recommendations:

The container labels proposed by GlaxoSmithKline are acceptable. An approval letter should be sent advising the applicant that this NDA labeling supplement is approved.

Robin Anderson, R.N., M.B.A.
Regulatory Review Officer

David Cummings
Chemistry Reviewer

cc:
HFD-590/ActingDivDir/R. Albrecht
HFD-590/Chem/D.Cummings
HFD-590/ChemTL/N.Schmuff
HFD-590/MedTL/R. Roca
HFD-590/PM/M.Bourg

Concurrence:
HFD-590/ActingDivDir/R. Albrecht 2/27/02
HFD-590/Chem/D.Cummings 2/20/02
HFD-590/ChemTL/N.Schmuff 2/20/02
HFD-590/MedTL/R. Roca 2/20/02

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/s/

Robin Anderson
2/27/02 02:26:06 PM
INTERDISCIPLINARY

Renata Albrecht concurred with this review on 2/27/02.

Renata Albrecht
2/28/02 08:55:28 AM
MEDICAL OFFICER