DRUG SAFETY AND EVALUATION BRANCH
CO-ORDINATION UNIT - APPLICATION ENTRY TEAM

A1

Document 2

FRONT DOOR FILTER COMMENT **Application No:**97.400.2

Date of Application Letter: 7 May 1997

Application to make 104 amendments to the Product Information for mefloquine hydrochloride (Lariam) tablets 250 mg and for approval of a CPI - ROCHE

Background: The company's covering letter outlines the background to this application and attached to this filter are relevant extracts from the Minutes of ADEC Meetings.

The application has been delayed awaiting the payment of an application fee.

Priority Evaluation: **NO**

Indications (as stated in proposed PI):

Malaria treatment: LARIAM is indicated for the treatment of acute attacks of malaria due to *P.falciparum* infection resistant to conventional antimalarial drugs.

Following therapy of mixed *P.falciparum/P.vivax* malaria with LARIAM relapse prophylaxis with an 8-aminoquinoline derivative (e.g. primaquine) should be considered in order to eliminate liver forms of *P.vivax*.

Malaria Prophylaxis: For travellers to countries with documented chloroquine and antifolate combination (FANSIDAR/Maloprim) resistant *P.falciparum* malaria, who are considered to be at high risk for malaria in view of their residence or travel ~~(of up to 3 months duration)~~ through rural areas (between the dusk to dawn period).

For travellers hypersensitive to sulphonamides and sulphones, who are considered to be at high risk for malaria in view of their residence or travel ~~(of up to 3 months duration)~~ through rural areas, (between the dusk to dawn period) in countries with high level chloroquine-resistant *P.falciparum* malaria.

Data Submitted:

PART 1	NIL	NIL	NIL
PART II	NIL	NIL	NIL
PART III	NIL	NIL	NIL
PART IV	1 Volume	1 copy	302 pages

Confidentiality Statement: None sighted

Ethics Certification: None

Statement re Individual Patient Data: None

Statement re Rejection USA/Canada: None

40

International Regulatory Status: None

Product Information/C.P.I. On files. There is a "compare" PI.

Presentation:
Volume labelling: Satisfactory
Pagination: Satisfactory
Page ranges: Stated on volume labelling

PART IV

Table of Contents to Clinical Data **YES**

Documentation provided consists of a series of references. Preceding is a list of the proposed changes linked to a reference where appropriate (Pages 1 to 4). On pages 5 and 6 there is an index to the references. Then follows a "compare" PI , a "clean" copy of the amended PI and a CPI.

*Legend: * Please note an item of importance that may require comment or review.*
Prepared by Margaret Morgan AET 5/6/97