

FROMMER LAWRENCE & HAUG LLP

745 FIFTH AVENUE NEW YORK, NEW YORK 10151

TEL: (212) 588-0800 FAX: (212) 588-0500

1113 10 10 04 10:40

WILLIAM S. FROMMER  
WILLIAM F. LAWRENCE  
EDGAR H. HAUG  
MATTHEW K. RYAN  
BARRY S. WHITE  
THOMAS J. KOWALSKI  
JOHN R. LANE  
DENNIS M. SMID\*  
DANIEL G. BROWN  
STEVEN M. AMUNDSON  
MARILYN MATTHEW BROGAN  
JAMES K. STRONSKI  
CHARLES J. RAUBICHECK  
GRACE L. PAN\*  
GORDON KESSLER  
MARK W. RUSSELL\*  
JEFFREY A. HOVDEN  
RONALD R. SANTUCCI  
RICHARD E. PARKE  
LEONARD J. SANTISI  
PORTER F. FLEMING

April 19, 2004

BY FEDERAL EXPRESS

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Re: Ribavirin, USP Tablets, 400 mg and 600 mg

SUITABILITY PETITION

A. THOMAS S. SAFFORD  
BARBARA Z. MORRISSEY  
Of Counsel

The undersigned submits this Suitability Petition in quadruplicate pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §355(j)(2)(C), and FDA regulations §§ 21 C.F.R. §§ 314.93, 10.20, 10.25 and 10.30.

BRUNO POLITO  
CHRISTIAN M. SMOLIZZA  
ROBERT E. COLLETTI  
DEENA LEVY WEINHOUSE  
DARREN M. SIMON  
JOHN G. TAYLOR  
DAVID A. ZWALLY  
SAMUEL H. MEGERDITCHIAN  
KEVIN MURPHY  
TERRI YOUNG NATALINE  
PEARL TENG LING SIEW  
TEDD W. VAN BUSKIRK  
STEPHEN J. LIEB  
FRANCINE S. ADLER, DPM  
HANS R. MAHR\*  
ARTHUR L. HOAC  
SANDRA KUZMICH, PH.D.  
SEAN J. GRYGIEL  
WENDY R. STEIN  
JOYCE W. LUK  
DILLON KIM  
LESLIE C. ALLEN\*  
NATHAN D. WEBER  
SAMUEL S. LEE\*  
PAMELA FEKETE  
ROBERT J. DEMENTO  
MAGALI ROZENFELD

**A. Action Requested**

This Suitability Petition requests a declaration by the Commissioner of Food and Drugs, head of the Food and Drug Administration ("FDA"), permitting the submission of an Abbreviated New Drug Application ("ANDA") for ribavirin, USP tablets in strengths of 400 mg and 600mg.

**B. Statement of Grounds**

- An ANDA may be submitted for the approval of a new drug that has the same active ingredient as a reference listed drug ("RLD"). 21 U.S.C. § 355(j)(2)(A)(ii)(I). An ANDA may also be submitted for a drug product whose strength differs from that of the RLD, upon FDA's approval of a suitability petition for such a change. 21 U.S.C. § 355(j)(2)(C).
- The specific RLD upon which this Suitability Petition is based is COPEGUS™ (ribavirin, USP) tablets, 200 mg (NDA 21-511 held by Roche Laboratories, Inc.), a drug which is indicated in combination with peginterferon alfa-2a for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and who have not been previously treated with interferon alpha. (See COPEGUS™ package insert and medication guide, Attachments 1 hereto).

2004 P.0196

CP1

- The proposed drug products will contain the same active ingredient as the RLD COPEGUS™, the same dosage form (tablet), and the same route of administration (oral). The proposed drug products will differ from the RLD only in the strengths offered. The RLD strength is 200 mg. The strengths of the proposed drug products will be 400 mg and 600 mg, respectively.
- The dosage strengths of ribavirin in the proposed drug products -- 400 mg and 600 mg -- fall squarely within the dosage range in the labeling of the RLD COPEGUS™. The labeled dose recommendations for the RLD are 800 mg to 1200 mg in two divided daily doses, individualized to the patient depending upon baseline disease characteristics (genotype), response to therapy and tolerability of the regimen (see Attachment 1, p. 20).
- The proposed dosage strengths of ribavirin 400 mg and 600 mg will afford patients the convenience of taking a single ribavirin tablet twice daily for the 800 mg or 1200 mg labeled dosages, rather than having to take 2 or 3 tablets twice daily to comply with these dosages, as is the case with the existing 200 mg ribavirin tablet. Thus, the proposed increased strengths will result in a decreased number of units of product the patient will have to take, thereby making it easier for patients to comply with their prescribed dosing schedule. In published studies, therapeutic compliance is cited as an important role in the overall success of treatment and improvement of outcomes.
- The labeling of the proposed drug product will be the same as the currently approved labeling for the RLD, except for changes which are required because of the difference of manufacturer, and the differences in strength as proposed under this Suitability Petition. (See proposed package insert and medication guide for the proposed 400 mg and 600 mg strengths of ribavirin, in Attachment 2 hereto).
- In view of the above, and because ribavirin, USP in combination with peginterferon alpha-2a has been marketed in the United States for almost 2 years with an established safety and efficacy profile (see Attachment 1), there is no reason to question the safety and effectiveness of the proposed ribavirin drug products.

### **C. Environmental Impact**

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

Dockets Management Branch  
Food and Drug Administration  
April 19, 2004  
Page 3

**D. Economic Impact**

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of this Suitability Petition.

**E. Pediatric Assessment**

A change in dosage strength does not require a pediatric assessment under the Pediatric Research Equity Act. (See 21 U.S.C. § 355b(a)(1)(A)).

**F. Certification**

The undersigned certifies that, to their best knowledge and belief, this Suitability Petition includes all information and views upon which the Petition relies, and includes representative data and information known to Petitioner which are unfavorable to the Petition.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By   
Charles J. Raubicheck

CJR:bav  
Attachments