

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for: 64-195**

**Application Number: 64-195**

**Trade Name: SangCya Oral Solution 100mg/ml**

**Generic Name: Cyclosporin Oral Solution [Modified]  
100mg/ml**

**Sponsor: Sangstat Medical Corporation**

**Approval Date: October 31, 1998**

**INDICATION(s): Kidney Liver and Heart Transplantation:  
for the prophylaxis of organ rejection in Kidney, Liver, and  
heart allogenic transplants and has been used in  
combination with azathioprine and corticosteroids.**

ANDA 64-195

JUL 31 1998

SangStat Medical Corporation  
Attention: Hana Berger Moran, Ph.D.  
1505 Adams Drive  
Menlo Park, CA 94025

Dear Madam:

This is in reference to your abbreviated new drug application dated November 21, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for SangCya™ Oral Solution (Cyclosporine Oral Solution, USP [Modified]), 100 mg/mL. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated March 3 and 9, May 12, June 30, July 20, August 13 and 24, and September 18, 25, and 29, and October 30, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your SangCya™ Oral Solution (Cyclosporine Oral Solution USP [Modified]), 100 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Neoral® Oral Solution, 100 mg/mL, of Novartis Pharmaceuticals Corp.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print.

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Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/s/

jr 10/31/98

Roger L. Williams, M.D.  
Deputy Center Director for  
Pharmaceutical Science  
Center for Drug Evaluation and Research