ANDA 65-003

May 12, 2000

Abbott Laboratories
Pharmaceutical Products Division
Attention: Alexa L. Chun, Ph.D.
D-491, Building AP6B-1
100 Abbott Park Road
Abbott Park, IL 60064-6108

Dear Madam:

This is in reference to your abbreviated new drug application dated December 19, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cyclosporine Capsules USP (Modified), 25 mg, 50 mg, and
100 mg. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

Reference is also made to your amendments dated July 20, and August 5, 1998; March 31, April 23, May 28, and December 7, 1999; and January 10, January 27, February 1, February 10, February 17, March 1, March 30 (2 amendments), and May 10, 2000.

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 Cyclosporine Capsules USP (Modified), 25 mg, 50 mg, and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Neoral**7** Capsules 25 mg, 50 mg, and 100 mg, respectively, of Novartis Pharmaceuticals Corp). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506(A) of the Act, 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 that 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. 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,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research