DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-546/S-031 and 20-336/S-013

Reliant Pharmaceuticals, LLC
Attention: Ms. Paulette Kosmoski
110 Allen Road
Liberty Corner, NJ 07938

Dear Ms. Kosmoski:

Please refer to your supplemental new drug applications dated December 22, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for (NDA 19-546/S-031) DynaCirc (isradipine) 2.5 and 5 mg Capsules and (NDA 20-336/S-013) Dynacirc CR (isradipine) 5 and 10 mg Controlled-Release Tablets.

We acknowledge receipt of your submission dated January 4, 2005.

These supplemental new drug applications provide for electronic draft labeling submitted in accordance to the Division's November 16, 2004 letter requesting angioedema be added to the **ADVERSE REACTIONS** section and the inclusion of a **Geriatric Use** subsection in the labeling.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted electronic labeling (package inserts submitted December 22, 2004).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDAs 19-546/S-031 and 20-336/S-013**." Approval of these submissions by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Ms. Denise M. Hinton
Regulatory Health Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge
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