



NDA 16-636/S-052, S-054

Endo Pharmaceuticals, Inc.
100 Painters Drive
Chadds Ford, PA 19317

Attention: Ira C. Lentz
Manager, Regulatory Affairs

Dear Mr. Lentz:

Please refer to your supplemental new drug applications dated February 21, 1995, and August 19, 1997, received February 24, 1995, and August 22, 1997, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Narcan (naloxone hydrochloride injection, USP).

We also acknowledge receipt of your submissions dated February 1, 2001 (S-054), and July 17, 2001 and January 8, 2002 (S-052, S-054).

The "Changes Being Effected" supplement S-052, proposed revisions in the INDICATIONS AND USAGE, CLINICAL PHARMACOLOGY, PRECAUTIONS, and OVERDOSAGE sections.

The "Changes Being Effected" supplement S-054, proposed revisions to comply with 21 CFR 201.57 and to add or strengthen safety information.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 8, 2002). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Shepherd, Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Cynthia McCormick
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