



NDA 18-780/S-095; NDA 18-781/S-089; NDA 19-717/S-069; NDA 20-100/S-032

Eli Lilly and Company
Attention: William L. Current, Ph.D.
Senior Associate Director, US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

SUPPLEMENT APPROVAL

Dear Dr. Current:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the products described below.

NDA No.	Supplement	Drug Product Name	Letter Date	Receipt Date	Amendment Dates
18-780	S-095	Humulin R (insulin human injection, USP [rDNA origin]), 100 IU/mL	28 Oct 2005	28 Oct 2005	10 Aug 2007
18-781	S-089	Humulin N NPH (human insulin [rDNA origin] isophane suspension), 100 IU/mL	28 Oct 2005	28 Oct 2005	7 Dec 2006 10 Aug 2007
19-717	S-069	Humulin Mix 70/30 (70% human insulin isophane suspension/30% human insulin injection [rDNA origin]), 100 IU/mL	28 Oct 2005	28 Oct 2005	10 Aug 2007
20-100	S-032	Humulin Mix 50/50 (50% human insulin isophane suspension/50% human insulin injection [rDNA origin]), 100 IU/mL	28 Oct 2005	28 Oct 2005	10 Aug 2007

We acknowledge receipt of your amendments listed above.

Your submission of August 10, 2007, to NDA 18-780/S-095 constituted a complete response to our June 20, 2006, action letter for that supplemental application.

These supplemental new drug applications provide for updating and consolidating the language in the patient labeling for the insulin products listed above.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the six patient package inserts [PPIs]). Upon receipt, we will transmit those versions to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “**SPL for approved NDA 18-780/S-095; NDA 18-781/S-089; NDA 19-717/S-069; NDA 20-100/S-032.**”

Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

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, call Enid Galliers, Chief, Project Management Staff, at 301-796-1211.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology
Products (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

NDA 18-780/S-095: PPI-R vial
NDA 18-781/S-089: PPI-N vial
NDA 18-781/S-089: PPI-N Pen
NDA 19-717/S-069: PPI-70/30 vial
NDA 19-717/S-069: PPI-70/30 Pen
NDA 20-100/S-032: PPI-50/50 vial

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

/s/

Hylton Joffe
8/22/2007 06:17:14 PM
Hylton Joffe for Mary Parks