



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-630/S-005

Abbott Laboratories  
200 Abbott Park Road, D-389, J45-2  
Abbott Park, IL 60064-6157

Attention: Kathryn B. Patterson  
Manager, Regulatory Affairs  
Hospital Product Division

Dear Ms. Patterson:

Please refer to your supplemental new drug application dated January 5, 2000, received January 6, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultiva (remifentanyl hydrochloride) for Injection.

We acknowledge receipt of your submissions dated December 17, 1999, September 6, October 18, and November 16, 2000, March 16, 2001, September 5, 2003, and March 8, 2004.

Your submission of September 5, 2003, constituted a complete response to our November 6, 2000, action letter.

This supplemental new drug application provides for revised labeling to include description of a clinical study of Ultiva vs Halothane in neonates and infants undergoing surgery for Pyloric Stenosis, extension of safety and efficacy of Ultiva as an analgesic agent for use in the maintenance of general anesthesia in outpatient and inpatient surgery down to the age of "birth," and extension of the doses for pediatric patients for maintenance of general anesthesia down to the age of "birth."

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with minor editorial revisions indicated in the enclosed labeling. These revisions are terms of the approval for this application.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-630/S-005." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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 Kim Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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

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Bob Rappaport  
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