



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-624/S-001

aaiPharma, Inc.  
2320 Scientific Park Drive  
Wilmington, NC 28405

Attention: Christy M. Clark  
Analyst, Regulatory Affairs

Dear Ms. Clark:

Please refer to your supplemental new drug applications dated June 24, and received June 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for methadone hydrochloride injection.

We acknowledge receipt of your submissions dated September 4, 2003, and January 12 and February 4, 2004.

Your submission of January 12, 2004 constituted a complete response to our December 24, 2003 action letter.

This supplemental new drug application provides for extensive revisions to the package insert.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and immediate container and carton labels).

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 21-624/S-001. Approval of this submission by FDA is not required before the labeling is used.

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 Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

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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/s/

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Bob Rappaport  
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