**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 10-996/S-068

aaiPharma Inc.
Attention: Veverly D. Lofton
Regulatory Affairs Professional
2320 Scientific Park Drive
Wilmington, North Carolina 28405

Dear Ms. Lofton:

Please refer to your supplemental new drug application dated November 25, 2003, received November 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Darvon Compound (propoxyphene hydrochloride, aspirin, and caffeine capsules, USP), 32 mg/389 mg/32.4 mg and 65 mg/389 mg/32.4 mg.

We acknowledge receipt of your submission dated May 21, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for aaiPharma facilities in North Carolina and New Jersey as alternate manufacturing and analytical testing sites for Darvon Compound 65 mg/389 mg/32.4 mg and the associated labeling.

We completed our review of this supplemental application, as amended. This supplement 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 submitted labeling (package insert submitted November 25, 2003 and immediate container labels submitted May 21, 2004).

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 10-996/S-068." 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 the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kathleen Reedy, Regulatory Health Project Manager, at 301-827-2090.

Sincerely,

*{See appended electronic signature page}*

John Smith, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

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/s/

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John Smith

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