LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

ATTACHMENT C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Lachman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Ave.
Suite 604
Westbury, NY 11590

DEC 20 2001

Docket No. 01P-0441/CP1

Dear Mr. Pollock:

This is in response to your petition filed on September 28, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydrocodone Bitartrate and Acetaminophen Tablets, 10 mg/300 mg. The listed drug product to which you refer in your petition is Norco® (Hydrocodone Bitartrate and Acetaminophen) Tablets, 10 mg/325 mg, approved under ANDA 40-248, held by Watson Laboratories Inc.

Your request involves a change in the strength of the acetaminophen component from that of the listed drug product (i.e., from 325 mg to 300 mg). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength of the acetaminophen component for the specific proposed drug product does not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug product are the same as that of the listed drug product. In addition, when an ANDA is submitted for your proposed drug product, the proposed labeling should reflect the maximum number of doses per day that can be administered for your proposed drug product. The total daily dose of the acetaminophen component should not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988) for information regarding the maximum daily dose of acetaminophen. In addition, a single dose of acetaminophen may not exceed 1000 mg. The total daily dose for hydrocodone bitartrate may not exceed 60 mg.

The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2001.

23RD EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF PHARMACEUTICAL SCIENCE
OFFICE OF GENERIC DRUGS

2003

ACETAMINOPHEN; CODEINE PHOSPHATE --

SUSPENSION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	AMARIN PHARMS	120MG/5ML;12MG/5ML	N86024 001	

CAPITAL AND CODEINE

AA	ALPHARMA	120MG/5ML;12MG/5ML	N85883 001	

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	ABLE	300MG;30MG	N40452 001	AUG 01, 2002
AA		300MG;60MG	N40459 001	AUG 01, 2002
AA	DURAMED PHARM BARR	300MG;15MG	N40223 001	NOV 18, 1997
AA		300MG;30MG	N40223 002	NOV 18, 1997
AA		300MG;60MG	N40223 003	NOV 18, 1997
AA	GENEVA PHARMS	300MG;30MG	N81250 001	JUL 16, 1992
AA		300MG;60MG	N81249 001	JUL 16, 1992
AA	IVAX PHARMS	300MG;60MG	N87083 001	
AA	MALLINCKRODT	300MG;15MG	N40419 001	MAY 31, 2001
AA		300MG;30MG	N40419 002	MAY 31, 2001
AA		300MG;60MG	N40419 003	MAY 31, 2001
AA	MIKART	300MG;30MG	N89238 001	FEB 25, 1986
+		650MG;30MG	N89231 001	MAR 03, 1986
+		650MG;60MG	N89363 001	SEP 09, 1991
AA	MUTUAL PHARM	300MG;15MG	N89671 001	FEB 10, 1988
AA		300MG;30MG	N89672 001	FEB 10, 1988
AA		300MG;60MG	N89673 001	FEB 10, 1988
AA	PHARMERAL	300MG;30MG	N87762 001	DEC 10, 1982
AA	PUREPAC PHARM	300MG;30MG	N86681 001	
AA	TEVA	300MG;15MG	N88627 001	MAR 06, 1985

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	TEVA	300MG;30MG	N88628 001	MAR 06, 1985
AA		300MG;60MG	N88629 001	MAR 06, 1985
AA	VINTAGE PHARMS	300MG;15MG	N89990 001	SEP 30, 1988
AA		300MG;30MG	N89805 001	SEP 30, 1988
AA		300MG;60MG	N89828 001	SEP 30, 1988
AA	WATSON LABS	300MG;15MG	N89997 001	DEC 28, 1994
AA		300MG;30MG	N89998 001	DEC 28, 1994
AA		300MG;60MG	N89999 001	DEC 28, 1994

ACETAMINOPHEN AND CODEINE PHOSPHATE #2

AA	SUPERPHARM	300MG;15MG	N89183 001	OCT 18, 1985

ACETAMINOPHEN W/ CODEINE NO. 3

AA	ROXANE	300MG;30MG	N84656 001	

ACETAMINOPHEN W/ CODEINE PHOSPHATE #3

AA	IVAX PHARMS	300MG;30MG	N85868 001	

TYLENOL W/ CODEINE NO. 1

+	ORTHO MCNEIL PHARM	300MG;7.5MG	N85055 001	

TYLENOL W/ CODEINE NO. 2

AA	+ ORTHO MCNEIL PHARM	300MG;15MG	N85055 002	

TYLENOL W/ CODEINE NO. 3

AA	+ ORTHO MCNEIL PHARM	300MG;30MG	N85055 003	

TYLENOL W/ CODEINE NO. 4

AA	+ ORTHO MCNEIL PHARM	300MG;60MG	N85055 004	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA	CENT PHARMS	500MG;5MG	N88898 001	MAR 27, 1985

ALLAY

AA	IVAX PHARMS	500MG;5MG	N89907 001	JAN 13, 1989

HYDROCET

AA	MALLINCKRODT	500MG;5MG	N89006 001	AUG 09, 1985