DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 23 2000

TRANSMITTED VIA FACSIMILE

Ernest Lengle, Ph.D.
Sr. Director, Regulatory Affairs
Watson Laboratories, Inc.
311 Bonnie Circle
Corona, CA 92882

RE: NDA 40-148
Norco (hydrocodone bitartrate and acetaminophen tablets, USP) 10 mg / 325 mg
MACMIS ID # 9430

Dear Dr. Lengle:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional material for Norco (hydrocodone bitartrate and acetaminophen tablets, USP), disseminated by Watson Laboratories, Inc. (Watson) that it is in violation of the Federal Food, Drug and Cosmetic Act (Act) and its implementing regulations. Specifically, we refer to a promotional flashcard, identified as W-10310A, that was disseminated at the promotional exhibit hall at the Scientific Assembly of the American Academy of Family Physicians held in Dallas, Texas, September 20, 2000 through September 24, 2000. Our specific objections follow:

Fair Balance

- Promotional materials are misleading if they fail to present information about the risks associated with the use of a drug with a prominence and readability reasonably comparable to that of claims for the drug. Your flash card contains numerous claims concerning the efficacy and safety of Norco, a narcotic analgesic. However, you have not presented any risk information concerning the contraindications, warnings, precautions, and adverse events associated with Norco's use. Therefore, your flashcard is lacking in fair balance.

Misleading Safety Claims

- Promotional materials are misleading if they suggest that a drug is safer, or has fewer side effects, than other products when such has not been demonstrated by substantial evidence. Your flashcard presents claims that suggest Norco has a superior safety profile compared to other hydrocodone combination products that contain acetaminophen. For example, you

present the headline, "A higher margin of safety," followed by the claim, "Reduces potential for hepatotoxcity." These claims suggests that Norco is associated with a reduced risk of hepatooxicity, as compared to other combination products, when such has not been demonstrated by substantial evidence.

Misleading Efficacy Claims

- You present the claim, "Can be more easily swallowed, and may enhance compliance." This claim suggests that Norco may enhance patient compliance compared to other 10 mg hydrocodone products. However, this claim is not supported by specific compliance data and is therefore misleading.

Failure to Submit

- Promotional materials must be submitted to the FDA under Form FDA 2253 at the time of initial dissemination. However, our records indicate your promotional flash card was not submitted at the time of initial use.

You should immediately cease distribution of this promotional flashcard and other similar promotional materials for Norco that contain the same or similar claims or presentations. You should submit a written response on or before November 6, 2000, describing your intent and plans to comply with the above. Your letter should include a list of materials discontinued and the date on which these materials were discontinued.

You should direct your response to me by facsimile at (301) 594-6771, or in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-17, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #9430 in addition to the ANDA number.

Sincerely,

/S/

Spencer Salis, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

WHEN PAIN PUSHES YOUR PATIENTS TO THEIR LIMIT... THEIR PAIN THERAPY DOESN'T HAVE TO

A HIGHER MARGIN OF SAFETY

The lowest level of acetaminophen (325 mg) of all 10 mg hydrocodone combination products[1]

Six tablets of NORCO® deliver less than half the recommended 4 gram daily limit of acetaminophen[1,2]

Reduces potential for hepatotoxicity[3]

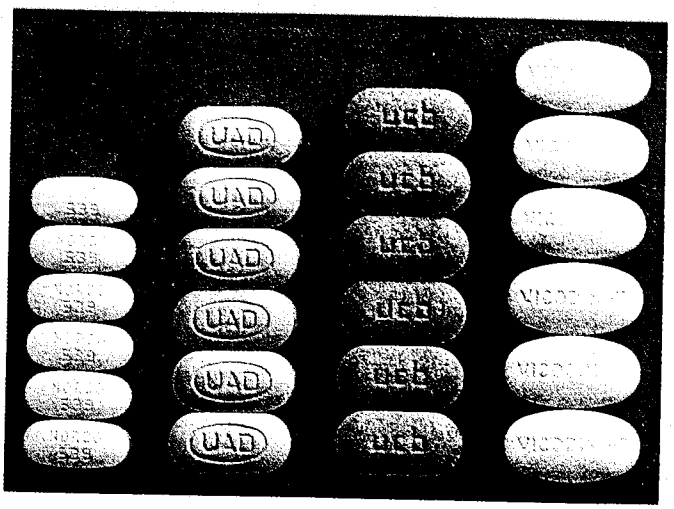
A PROVEN LEVEL OF PAIN RELIEF

The highest dose of hydrocodone available in a single tablet[1]

NORCO® C III
HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS, USP
10 mg/325 mg
10/325

NORCO® C III

HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS USP 10 mg/ 325 mg



SMALLEST TABLET SIZE OF ALL 10 MG HYDROCODONE PRODUCTS

Can be more easily swallowed, and may enhance compliance

LOWER COST

NORCO® is the least expensive of all branded 10 mg hydrocodone products[4]

TELEPHONE PRESCRIBING CONVENIENCE

Schedule III designation allows call-in prescriptions and refills in most states, with no need for triplicate prescription blanks

FORMULATION	AWP[4]/BOTTLE (100's)
NORCO® (10/325)	$54.73
Lorcet® 10/650	$88.34
Lortab® 10/500	$62.67
Vicodin HP® (10/660)	$77.99

Lorcet® 10/650 is a registered trademark of Forest Pharmaceuticals, Inc.
Lortab® 10/500 is a registered trademark of UCB Pharma, Inc.
Vicodin HP® (10/660) is a registered trademark of Knoll Pharmaceutical Co.

References

1. *Drug Facts and Comparisons®*. St. Louis, MO: Facts and Comparisons, Inc. 1997.
2. Schiødt FV, Rochling FA, Casey DL, Lee WM. Acetaminophen toxicity in an urban county hospital. *N Engl J Med*. 1997;337(16):1112–1117.
3. Hench PK, Weart CW, Whitcomb DC. Acetaminophen toxicity: When to worry, what to do. *Patient Care*. 1996;30(1):87–101.
4. *The Prescription Pricing Guide*. Indianapolis, IN: Medi-Span, Inc. April 1998 update.

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Laboratories, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc.