INTERNATIONAL REGULATORY BUSINESS CONSULTANTS, L.L.C.

Ira R. Berry, President

6799 '03 OCT -9 P1:30

October 2, 2003

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
12420 Parklawn Drive (Room 1-23)
Rockville, MD 20857

RE: SUITABILITY PETITION

Dear Madam/Sir:

Enclosed are four copies of this Suitability Petition filed by the undersigned under 21 CFR 314.93.

It is requested that the Commissioner makes a determination that the drug product described hereinafter is suitable for consideration as an Abbreviated New Drug Application (ANDA) under 21 CFR 314.93(b).

Sincerely,
INTERNATIONAL REGULATORY BUSINESS CONSULTANTS, L.L.C.

Ira R. Berry

Enclosure: Four (4) copies
Certified Mail – Return Receipt Requested

2003P-0475

CP1

Suitability Petition

Petition Filed By:

International Regulatory Business Consultants, L.L.C.
2115 Millburn Avenue, Suite 108
Maplewood, NJ 07040

Proposed Product:

Oral Solution Dosage Form Containing
Hydrocodone Bitartrate 5 mg/ Acetaminophen 325 mg

Table of Contents

Suitability Petition

International Regulatory Business Consultants, L.L.C. submits this Suitability Petition under Section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 355 (j)(2)(C), which authority has been delegated to the Commissioner of Food and Drugs (Commissioner) under CFR §5.10. Petitioner requests the Commissioner to make a determination that the drug products hereinafter described are suitable for consideration as an Abbreviated New Drug Application (ANDA) under CFR §314.93 (b).

A. Action Requested

International Regulatory Business Consultants, LLC requests a determination that a drug product containing hydrocodone bitartrate 5 mg and acetaminophen 325 mg in liquid form for oral administration is suitable for evaluation under an ANDA.

NORCO® (hydrocodone bitartrate 5 mg and acetaminophen 325 mg) is listed in the Orange Book as the reference listed drug (See Attachment 1). The actives and strengths are the same. We request the Commissioner to grant the hydrocodone bitartrate 5 mg and acetaminophen 325 mg liquid suitable for submission as an ANDA.

We also request the Commissioner to grant a waiver from the requirements of the pediatric study for a change in dosage form from tablet to oral solution on the basis that these active ingredients are currently approved by the Food and Drug Administration at the same strengths and all for the same disease conditions. We understand the Agency's desire to seek information regarding the use of this drug in various pediatric populations.

However, in this case, the approved product labeling already includes uses and dosing instructions for the most significant patient population. We propose that the concept of a standardized dosage adjustment for safety and efficacy, which is the usual goal of pediatric studies, is not relevant to this drug. In accordance with 21 CFR 314.55(c) the Commissioner may grant full or partial waiver of the study requirements on his own initiative **or** at the request of the applicant.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act allows an ANDA applicant to petition the FDA for permission to file an ANDA for a drug product identical to those approved via new drug applications as identified in the "Orange Book" published by the FDA. Where the proposed drug product differs from the "listed drug" in one or more respects, a person may petition the Agency, under section 505(j) (2) of the Act, for a determination that the proposed drug is suitable to be submitted as an ANDA. The listed product that forms the basis for this petition is Watson Pharmaceuticals, hydrocodone bitartrate 5 mg and acetaminophen 325 mg tablets, NORCO®, (NDA 040099). See (Attachment 4). To the best of the petitioner's knowledge, there are no expired or pending U.S. patents for the listed product. Further, hydrocodone bitartrate and acetaminophen oral solution products have been previously approved and have been identified as listed drug products (See Attachment 3).

The proposed product differs from the listed drug only in regards to dosage form (oral solution instead of a tablet). Otherwise, the proposed drug product is identical with respect to active ingredients, strength, route of administration and conditions of use.

The legal basis under which this application proceeds is promulgated in the CFR Section noted above, which allows the Commissioner to accept a generic drug application for a drug which differs in dosage form from the pioneer or reference drug product. The petitioner is not aware of any information that would be unfavorable to the granting of the requested action.

1. Identification of Reference Listed Drug (RLD)

Attached is the labeling for the RLD product to which we are comparing the proposed drug which contains hydrocodone bitartrate 5 mg and acetaminophen 325 mg (See Attachments 1 and 4).

Application No.

040099

(Strength) Name of Drug:

(hydrocodone bitartrate 5 mg, USP, and acetaminophen 325 mg, USP) NORCO®.

Company

Watson Pharmaceuticals, Inc.

2. Labeling Differences

Attached are copies of the proposed generic labeling in draft form (See Attachment 5) and copies of the reference drug labeling (See Attachment 4). Please note that the final design for the product container label and name have not been established and will be established once the manufactured for client is identified. Additionally, the label does not have the expiration and lot number printed directly on the label, it will be printed during packaging.

The following is a description of the differences between the proposed generic product and the RLD package inserts.

PACKAGE INSERT

1. Remove Norco® 5/325
2. Replace "**NORCO®** (*acetaminophen and hydrocodone bitartrate) Tablets USP*" trade name to the generic name of "Hydrocodone Bitartrate and Acetaminophen Oral Solution "
3. Replace "Rev. 06/02" with "ISS XX/XX."
4. Replaced "Code 667C00" with "PSLXXXXXX"

FROM:	**TO THE FOLLOWING:**
NORCO® 5/325 **HYDROCODONE BITARTRATE AND ACETAMINOPHEN** **TABLETS USP** **5 mg/325 mg** **R_x only** Rev. 06/02 Code 667C00	**HYDROCODONE BITARTRATE AND ACETAMINOPHEN** **ORAL SOLUTION USP** **5 mg/325 mg** **R_x only** ISS XX/XX PSLXXXXXX

DESCRIPTION

A. Replace the trade name with the generic name indicated

B. Replace "tablet" with "liquid"

C. Add "Alcohol 7 %"

D. Replaced "NORCO® 5/325 tablet" with "This product"

FROM:

DESCRIPTION
Norco® (Hydrocodone bitartrate and acetaminophen) is supplied in tablet form for oral administration.

Each NORCO® 5/325 tablet contains:
Hydrocodone Bitartrate.....5 mg
Acetaminophen.....325 mg

In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, crospovidone, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, and sugar spheres which are composed of starch derived from corn, sucrose, and FD&C Yellow #6. Meets USP Dissolution Test 1.

TO THE FOLLOWING:

DESCRIPTION
Hydrocodone Bitartrate and Acetaminophen Oral Solution is supplied in liquid form for oral administration.

This product contains:	Per 5 mL
Hydrocodone Bitartrate, USP	5 mg
Acetaminophen, USP	325 mg
Alcohol	7 %

In addition, the liquid contains the following inactive ingredients: citric acid anhydrous, ethyl maltol, glycerin, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, sorbital solution, sucrose, with D&C Yellow #10 and FD&C Yellow #6 as coloring and natural and artificial flavoring.

A. Replaced trade name with the generic name indicated

CONTRAINDICATIONS

A. Replaced trade name with the generic name indicated

PRECAUTIONS

A. Replaced trade name with the generic name indicated

DRUG ABUSE AND DEPENDENCE

A. Replaced trade name with the generic name indicated

DOSAGE AND ADMINISTRATION

A. Replaced "tablets" with "teaspoonfuls"

FROM:	TO THE FOLLOWING:
DOSAGE AND ADMINISTRATION Dosage should be adjusted according to severity of pain and response of the patient. However, it should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related. The usual adult dosage is one or two tablets every four to six hours as needed for pain.	**DOSAGE AND ADMINISTRATION** Dosage should be adjusted according to severity of pain and response of the patient. However, it should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related. The usual adult dosage is one or two teaspoonfuls every four to six hours as needed for pain. The daily dose for adults should not exceed 6 teaspoonfuls.

HOW SUPPLIED

FROM:

HOW SUPPLIED
Norco® 5/325 tablets (Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/325 mg) contain hydrocodone bitartrate 5 mg and acetaminophen 325 mg. They are supplied as white with orange specks, capsule-shaped, bisected tablets, debossed Watson on one side and 913 on the other side, in bottles of 100 tablets, NDC 52544-913-01, in bottles of 500 tablets, NDC 52544-913-05, and in hospital unit-dose cartons of 100 tablets (25 tablets x 4 cards), NDC 52544-913-48.

Storage: Store at controlled room temperature, 15°-30°C (59°-86° F).
Dispense in a tight, light-resistance container with child-resistance closure.

A Schedule CIII Narcotic.

Manufactured for
WATSON PHARMA, INC.

A subsidiary of
Watson Laboratories, Inc.
Corona, CA 98880 USA

Manufactured by
Mikart, Inc.
Atlanta, GA 30318

Rev. 06/02 Code 667C00

TO THE FOLLOWING:

HOW SUPPLIED
Hydrocodone Bitartrate and Acetaminophen Oral Solution containing hydrocodone bitartrate 5 mg and acetaminophen 325 mg per 5 mL with 7 % alcohol. It is supplied in containers of 1 pint (473 mL) NDC XXXXX-XXX-XX.

Storage: Store at controlled room temperature, 15°-30°C (59°-86° F).
Dispense in a tight, light-resistance container with child-resistance closure.

A Schedule CIII Narcotic.

Manufactured for
XXXXXX

Manufactured by
XXXXXX

ISS XX/XX PSLXXXXXX

C. Environmental Impact

International Regulatory Business Consultants, L.L.C., hereby requests a categorical exclusion from the requirement of preparing an environmental assessment. As provided in 21 CFR 25.31, neither an environmental assessment nor an environmental impact statement is required. To the best of the petitioner's knowledge, no extraordinary circumstances exist that may significantly affect the human environment as discussed under 21 CFR 25.21.

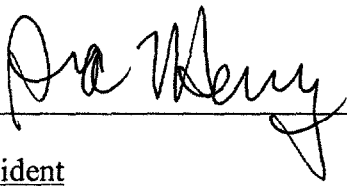
D. Economic Impact

As provided in 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to us that are unfavorable to the petition.

Typed Name: Mr. Ira R. Berry

Signature: 

Title: President

Name of Petitioner: International Regulatory Business Consultants, L.L.C.

Mailing Address: 2115 Millburn Ave.
Suite 108
Maplewood, NJ 07040

Telephone No: 973-275-5300