CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 11522, S010

APPROVAL LETTER

NDA 11-522 / S-010

FEB 13 1996

Richwood Pharmaceutical Company, Inc.
Attention: William A. Nuerge
Chief Operating Officer
7900 Tanner's Gate Drive, Suite 200
Florence, KY 41042

Dear Mr. Nuerge:

Please refer to your supplemental new drug application of September 21, 1995 (S-010), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adderall (dextroamphetamine saccharate, dextroamphetamine sulfate, amphetamine aspartate, and amphetamine sulfate) 10 mg and 20 mg tablets.

Supplemental application S-010 consists of the resubmission and provides critical analyses for the quantitation of d- and l-amphetamine, and updated manufacturing, controls and test procedures. The supplemental application also provides draft labeling revised in response to the Federal Register notice of August 8, 1970 (DESI 5378), classifying this drug effective for use in the treatment of narcolepsy, attention deficit disorder with hyperactivity, and exogenous obesity.

We have completed the review of this supplemental application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended with the labeling changes listed below. Accordingly, the application, with these labeling revisions, is approved effective as of the date of this letter. This action also approves this application on the basis of effectiveness of the drug as well as safety and supersedes the Federal Register notice of September 25, 1973, thus re-establishing the approval of NDA 11-522.

The labeling revisions, as agreed to by Rob Falconer of your firm during his telephone conversation with Steven D. Hardeman, R.Ph., of this agency on January 26, 1996, are as follows:

1. The statement currently placed in Warnings, "*Clinical experience suggests ... growth should be monitored during treatment.*" should not be repeated under Precaution--Pediatric Use.

2. The statement under Precautions that FD&C Yellow #6 causing allergic reactions is unnecessary and should be deleted, as this statement applies to FD&C Yellow #5 rather than #6.

3. Under Adverse Reactions--Cardiovascular, the statement, "There have been isolated reports of cardiomyopathy associated with chronic amphetamine use," should be added

4. The treatment of overdosage section should be updated, as follows:
(additions are in redline font, deletions are in strikeout font)

OVERDOSAGE:

TREATMENT--Consult with a Certified Poison Control Center for up to date guidance and advice. Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage, administration of activated charcoal, administration of a cathartic and sedation Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine excretion, but is believed to increase risk of acute renal failure if myoglobinuria is present. If acute, severe hypertension complicates amphetamine overdosage, administration of intravenous phentolamine (Regitine®, CIBA) has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

We also have the following request and acknowledgment regarding chemistry and manufacturing controls:

1. We request that you place all 6 validation batches on long-term stability at ambient (i.e, either 30°/ambRH or 25°/60%RH) conditions. Please provide your stability protocol and commitment (i.e. storage conditions, sampling times, and tests to be performed).

2. As requested, a 24-month expiration dating period at ambient conditions is acceptable.

These revisions are terms of the supplement approval. Marketing the product before making, exactly as agreed to, the revisions in the products's labeling may render the product misbranded and an unapproved new drug

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed or 6 months from the date of this letter. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 11-522 / S-010. Approval of this labeling by FDA is not required before it is used. Should additional information relating to the safety and effectiveness of the drug become available, further revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact Steven D Hardeman, R.Ph., Regulatory Management Officer, at (301)594-2777.

Sincerely yours,

Robert Temple 2/12/96

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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MEDICAL REVIEW(S)

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