

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

75-217

APPLICATION NUMBER:

ADMINISTRATIVE DOCUMENTS

ANDA 75-217 APPROVAL SUMMARY

DRUG PRODUCT: Ibuprofen Oral Suspension, USP

FIRM: L. Perrigo Company

DOSAGE FORM: Oral Suspension

STRENGTH: 40 mg/mL

cGMP STATEMENT/EIR UPDATE STATUS: EER Acceptable Date June 12, 1998

BIO STUDY: APPROVE, Letter Sent on February 27, 1998

VALIDATION: DS and DP are compendial. However, since some of the firm's methods are in-house, method validation by Detroit District Lab. was requested. Method Verification report dated April 28, 1998 is satisfactory.

STABILITY: Three months of accelerated, 40°C/75% RH, and three months room temperature, 25°C-30°C, data in the market package sizes, 1/2 fluid ounce, and 1 fluid ounce provided. The container/closure system used for the stability study is equivalent to the system proposed for commercial use. All reported data are within specifications as listed. Thus, a 24 month expiration date is justified.

Tests and specifications for the drug product on stability include:
description, container/closure, viscosity pH
ibuprofen assay dissolution

and impurities ()

Microbiological Specifications: Aerobic plate count
mold & yeast count
aeruginosa, and E. Coli . . . preservative challenge

LABELING: APPROVE, Review Date May 6, 1998

STERILIZATION VALIDATION (IF APPLICABLE): N/A

SIZE OF BIO BATCH: The bio batch (#7P404V), size
is also the test batch. The DS supplier is
is adequate as of March 6, 1998.

SIZE OF STABILITY BATCHES: Stability batch is the same as the biobatch.

PROPOSED PRODUCTION BATCHES: Production batch size is the same as
the test batch size, The manufacturing
process for the proposed production runs also remains the same as that
used for the test batch.

CHEMIST:

[Handwritten Signature]

DATE:

2/17/98

SUPERVISOR:

[Handwritten Signature]

DATE:

2/13/98

Telecon

Date: 111097

Time: 1000

ANDA #: 75-217

Firm: L. Perrigo Co.

Drug: Ibuprofen oral drops, 40 mg/mL

Participants: Gregg Davis, FDA and Brian Schuster, Perrigo

Agenda:

I called Brian Schuster for a reconciliation sheet for the packaging. It is very unclear in the batch records how much was actually packaged and in which size bottles. He said he will fax the info and follow with a hard copy labeled as correspondence.