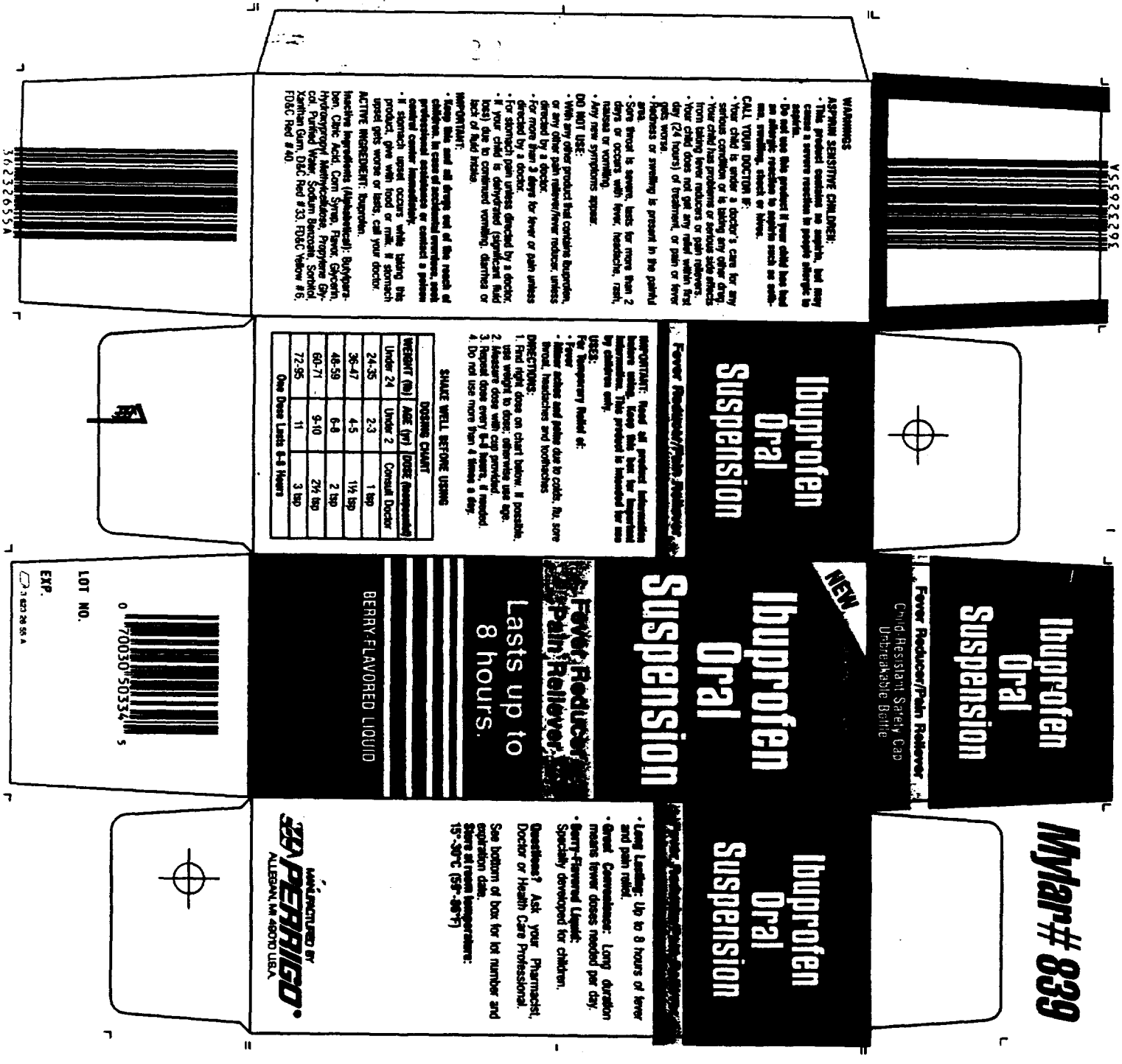
CENTER FOR DRUG EVALUATION AND RESEARCH

74-937

APPLICATION NUMBER:

APPROVED DRAFT LABELING

Final Printed Labeling
Ibuprofen Oral Suspension
100 mg/5 mL
ANDA 74-937
4 oz. Carton



{Lot number and expiration date will appear on carton.}

SEP 5 1997

ANDA 74-937

L. Perrigo Company
Attention: Brian R. Schuster
117 Water Street
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application dated July 26, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ibuprofen Oral Suspension USP, 100 mg/5 mL.

Reference is also made to your amendments dated November 13, 1996; February 14, March 7, June 23, and August 22, 1997.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted Over-the-Counter (OTC) labeling. Therefore, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product), and is therefore subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under Section 505(j)(4)(B)(iv) of the Act. At a future date the Office of Generic Drugs (OGD) will notify you of any determination concerning the 180-day exclusivity provisions as they may relate to this application.

The listed drug product referenced in your application is subject to a period of patent protection which expires on December 20, 2011, (patent 5,374,659) and new product exclusivity which expires on June 16, 1998. Your application contains a Paragraph IV certification to patent 5,374,659 under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(4)(B)(iii) of the Act provides that "approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided

under paragraph (2)(B)(I) is received." You have notified FDA that L. Perrigo Company (Perrigo) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Perrigo within the statutory forty-five day period.

Please provide the Agency, at least 60 days prior to the expiration of the applicable exclusivity protection (June 16, 1998), an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. If not previously notified by OGD, you should specifically request that a determination be made concerning the 180-day exclusivity provisions as they may relate to this application. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above. Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter, or delay in issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under 21 U.S.C. 355. The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

Prior to submitting the amendment, please contact Mr. James Wilson, III, Project Manager, at (301) 827-5848 for further instructions.

Sincerely yours,

9/5/97

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research