

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

103471

APPROVABLE LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Carl Sze

JUN 03 1993

Our Reference No: 92-0495

Bernardita Mendez, Ph.D.
Chiron Corporation
4560 Horton Street
Emeryville, CA 94688-2916

Dear Dr. Mendez:

This letter is in regard to your Product License Application for Interferon beta-1b, submitted under section 351 of the Public Health Service Act. Reference is also made to our information requests dated January 12, 1993, April 27, 1993 and your responses dated March 9, 1993 and May 11, 1993.

The Center for Biologics Evaluation and Research (CBER) has completed the review of this application and has determined it to be approvable. However, before final approval action may be taken you are required to submit the following:

1. revised final product labeling which adequately resolves our preliminary review comments dated May 11, 1993 and all subsequent labeling review comments, including review comments transmitted by facsimile on June 2, 1993 and those communicated during a May 14, 1993 teleconference between Dr. Paul Leber of the Division of Neuropharmacology, Center for Drug Evaluation and Research, and representatives of Chiron and Berlex Laboratories;
2. a revised postmarketing commitment letter which identifies satisfactory proposals for study endpoints and plans for postmarketing clinical studies; and
3. data validating procedures used to ship final container material to the Berlex Laboratories (Wayne, New Jersey) distribution center (these data should be submitted to your establishment license application 92-0494).

You may request a meeting with CBER to discuss the above steps for approval. Please request the meeting at least 15 days prior to the meeting date. Alternatively, you may choose to discuss the above steps via a telephone call. Should you wish this meeting or a telephone discussion, please call Dr. J. Lloyd Johnson, in the Division of Establishment Licensing, at 391-295-9049.

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Within 10 days after the date of this letter, you are requested to amend the application or to notify us of your intent to file an amendment and provide us with the status of the above requested information. If the information is not supplied the application may be considered not approvable and CBER may take action to deny it.

You may not legally market this product until FDA notifies you in writing that the application is approved.

Sincerely yours,

Janet Woodcock, M.D.
Acting Director
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

cc: Dr. Lerner, HFM-505
Dr. Gerrard, HFM-505
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