



Our STN: BL 103471/5032

OCT 10 2003

Chiron Corporation
Attention: Mr. Donald Gay
Director, Regulatory Affairs
4560 Horton Street
Emeryville, CA 94608-2916

Dear Mr. Gay:

Your request to supplement your biologics license application for Interferon beta-1b, to provide for the use of diluent in a prefilled syringe, instead of a vial configuration, has been approved.

FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208. FDA hereby approves the revised Medication Guide you submitted on October 9, 2003.

Please note that:

- this Medication Guide must be reprinted at the end of the package insert [21 CFR 201.57(f)(2)];
- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208];
- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and
- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided.

Please submit final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see <http://www.fda.gov/cber/transfer/transfer.htm> and <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-16242.html>. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

CBER Document Control Center
Attn: Office of Therapeutics Research and Review
Suite 200N (HFM-99)
1401 Rockville Pike
Rockville, Maryland 20852-1448

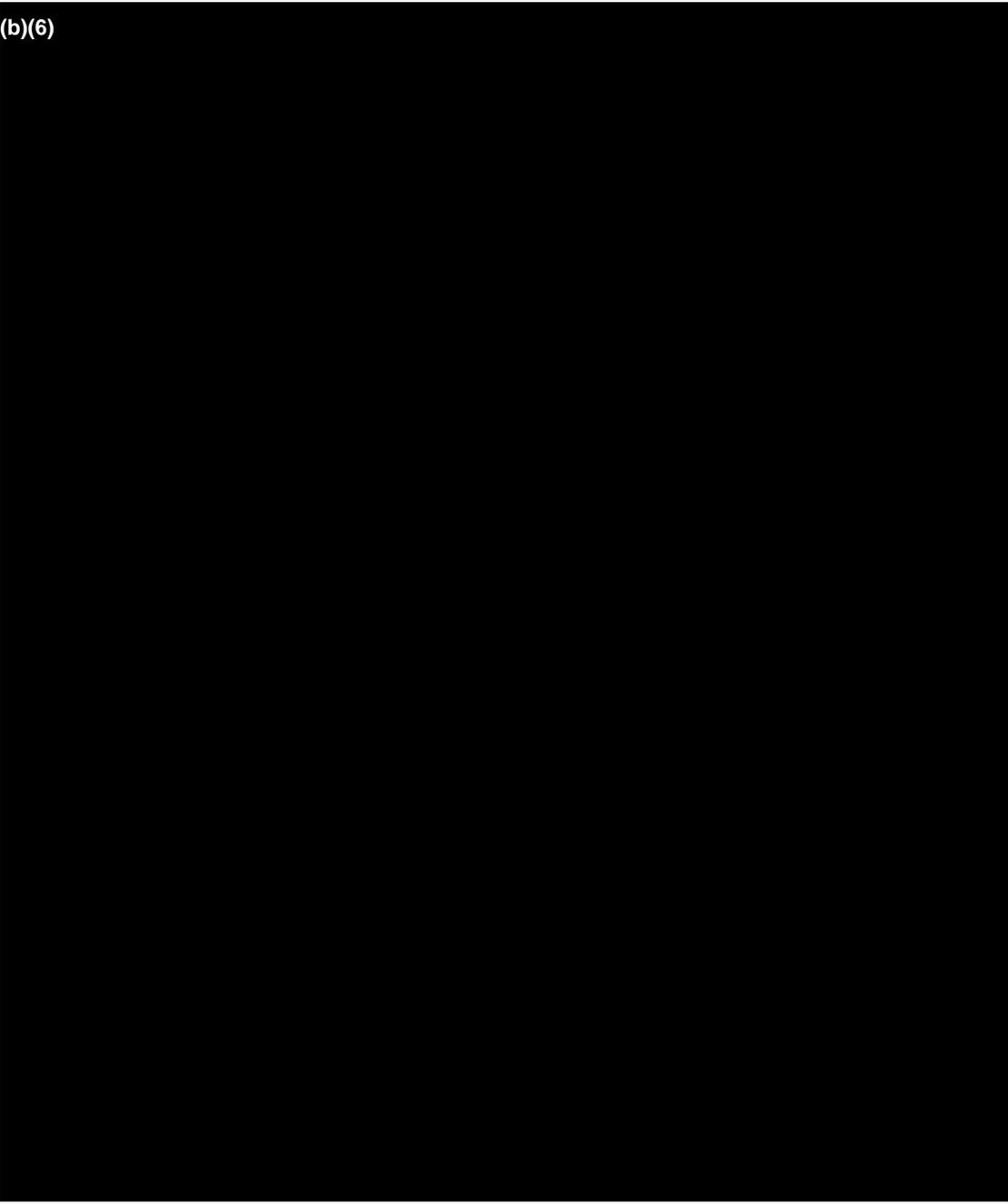
This information will be included in your biologics license application file.

Sincerely,

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Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Office of New Drugs
Center for Drug Evaluation and Research

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