

Food and Drug Administration
Rockville MD 20857

APR 8 2002

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Robert P. Brady
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Sent by Facsimile and U.S. Mail

Reference Number: OGD # 01-583

Dear Mr. Brady:

This responds to your letter of November 21, 2001, concerning Abbreviated New Drug Applications (ANDAs) referencing Schering's Rebetol® (ribavirin) (NDA 20-903). You represent ICN Pharmaceuticals, Inc. (ICN), which holds two patents that are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for Rebetol®. These are U.S. Patent No. 5,767,097 (the '097 patent) and U.S. Patent No. 6,063,772 (the '772 patent).¹ Your letter seeks assurance that FDA will require ANDA applicants to submit patent certifications under section 505(j)(2)(A)(vii)(III) or (IV) of the Federal Food, Drug, and Cosmetic Act (the Act) for these patents, and will not permit submission of a statement under section 505(j)(2)(A)(viii) (a section viii statement).

The agency has reviewed the record in this matter, and determined it would not be appropriate for any ANDA applicant referencing Schering's Rebetol® to submit a section viii statement for the '097 or '772 patent. Therefore, FDA will require any ANDA referencing Rebetol® to contain a paragraph III or paragraph IV certification for the '097 and '772 patents.

If you have further questions regarding this issue, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at (301) 827-5845.

Sincerely,

Gary Buchler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

¹ Your November letter stated that you intended to submit U.S. Patent No. 6,150,337 to FDA for listing as well, but the agency has no record of having received this patent.