DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-192

APR 6 2004

Sandoz, Inc.
Attention: Pankaj Dave, Ph.D.
2400 Route 130 N
Dayton, NJ 08810

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 22, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ribavirin Capsules, 200 mg.

Reference is also made to your amendments dated April 4, May 8, May 13, May 23, July 18, July 21, December 17 and December 29, 2003; and February 20, March 9, March 23, March 24, March 27, and March 30, 2004. We also acknowledge receipt of your correspondence dated August 20, 2001; January 23, February 7, November 13, November 18, December 4, and December 26, 2002; March 28, April 15, May 13, July 15, September 22, October 15, 2003; and February 3, and March 26, 2004, addressing the patent and exclusivity issues noted below.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Ribavirin Capsules, 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Rebetol Capsules® 200 mg, of Schering Plough Research Institute. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product referenced in your application, Rebetol® Capsules, 200 mg, of Schering Plough Research Institute, is subject to multiple periods of patent protection. The following United States patents and their expiration dates currently appear in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

Patent Number	Expiration Date
5767097 (the '097 patent)	January 23, 2016
6063772 (the '772 patent)	January 23, 2016
6177074 (the '074 patent)	November 01, 2016
6524570 (the '570 patent)	November 01, 2016
6461605 (the '605 patent)	November 01, 2016
6472373 (the '373 patent)	September 21, 2017
6172046 (the '046 patent)	September 21, 2017
6337090 (the '090 patent)	December 22, 2017
6335032 (the '032 patent)	December 22, 2017
5914128 (the '128 patent)	December 22, 2017
6051252 (the '252 patent)	December 22, 2017

Your application contains paragraph IV patent certifications to patents '097, '128, '252, '772, '046, '090, '032, '605 and '373 under Section 505 (j)(2)(A)(vii)(IV) of the Act stating that the claims of these patents will are invalid, unenforceable, and/or will not be infringed by your manufacture, use, or sale of your Ribavirin Capsules, 200mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought against Sandoz, Inc. (Sandoz) for infringement of one or more of the patents which were the subjects of the paragraph IV certifications. This infringement action must be brought against Sandoz before the expiration of forty-five days from the dates the notices that Sandoz provided under paragraph (2)(B)(i) were received by the NDA and patent holders. You have notified the agency that Sandoz complied with the requirements of Section 505(j)(2)(B) of the Act, and that Schering Corporation initiated patent infringement actions against you regarding the '128, '252, '032 and '090 patents in United States District Court for the District of New Jersey (Schering Corporation v. Geneva Pharmaceuticals Technology Corporation (now Sandoz, Inc.), Civil Action No. 01-4556 ['128 and '252 patents] and 02-1564 ['032 and '090 patents]). You notified the Agency that on July 22, 2003, U.S. District Judge Dennis M. Cavanaugh entered a Stipulated Order of Dismissal with prejudice regarding the above-identified actions.

ICN Pharmaceuticals, Inc. also brought a patent infringement action against you regarding the '097 and '772 patents in United States District Court for the Central District of California (ICN Pharmaceuticals, Inc., et. al. v. Geneva Pharmaceuticals Technology Corp., et. al., Case No. CV-02-3544-MRP; subsequently consolidated with Case No. CV-02-3543-MRP, Case No. CV-02-8142-

MRP, and Case No. CV-029-358-MRP). You have also notified the Agency that on July 14, 2003, U.S. District Judge Mariana R. Pfaelzer granted the defendants joint Motion for Summary Judgement of Non-Infringement with regard to the '097 and '772 patents.

In addition, your application contains patent statements under Section 505(j)(2)(A)(viii) of the Act indicating that the '074 and '570 patents are method of use patents, and that these patents do not claim any of the proposed indications for which you are seeking approval. Furthermore, you have informed the Agency that no legal action regarding the '046 patent was brought against Sandoz within the forty-five day statutory period.

With this approval, Sandoz is eligible for 180-day generic drug marketing exclusivity for Ribavirin Capsules, 200 mg, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the Agency has concluded that Sandoz was the first ANDA applicant to submit a substantially complete ANDA containing paragraph IV certifications to the '097, '128, '252, '772 and '046 patents. We note that Sandoz's eligibility for 180-day exclusivity with respect to the '772 and '097 patents has expired because it was "triggered" by the July 17, 2003, court decision. However, an another ANDA applicant was first to submit a substantially complete ANDA containing paragraph IV certifications to the '032, '090, '605 and '373 patents. Thus, Sandoz will share the 180-day generic drug marketing exclusivity with another ANDA applicant. The shared market exclusivity will begin to run on the date either ANDA applicant begins first commercial marketing of the drug product. The basis for the Agency's granting shared eligibility for 180-day generic drug marketing exclusivity for Ribavirin Capsules, 200 mg, is explained in detail in a separate letter issued to Sandoz concurrently with this approval letter.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that Sandoz will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date Sandoz commenced commercial marketing of this product.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

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