DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 75-593

JUN 9 2004

Dr. Reddy's Laboratories Inc.
Attention: William R. McIntyre, Ph.D.
U.S. Agent for: Dr. Reddy's Laboratories Limited
200 Somerset Corporate Boulevard, 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 26, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ciprofloxacin Tablets USP, 100 mg, 250 mg, 500 mg, and 750 mg.

Reference is also made to the Tentative Approval letters issued by this office on December 22, 2000, and August 22, 2002, and your amendments dated November 20, 2003, March 31, May 18, June 2, and June 7, 2004.

We have completed the review of this tentatively approved 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 Ciprofloxacin Tablets USP, 100 mg, 250 mg, 500 mg, and 750 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Cipro Tablets 100 mg, 250 mg, 500 mg, and 750 mg, respectively, of Bayer Pharmaceuticals Corporation (Bayer). 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 (RLD) referenced in your application, Cipro Tablets of Bayer Pharmaceuticals Corp., is subject to periods of patent protection and market exclusivity. The following patents are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book".

U.S. Patent No.	Expiration Date
4,670,444 (the '444 patent)	December 9, 2003
5,286,754 (the '754 patent)	February 15, 2011

Your application contains a paragraph IV certification to the '754 patent under §ection 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use or sale of this drug product will not infringe the '754 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought against Dr. Reddy's Laboratories Limited (Dr. Reddy) for infringement of the '754 patent prior to the expiration of 45 days from the date the notice you provided under Section 505(j)(2)(B) was received by the owner of the new drug application (NDA) for the reference listed drug product and the patent holder. You have notified the agency that Dr. Reddy complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement of the '754 patent was brought against Dr. Reddy within the statutory 45 day period.[1]

Your application formerly contained a paragraph IV certification to the `444 patent, but now contains a paragraph II certification to the '444 patent under Section 505 (j)(2)(A)(vii)(II) of the Act. The '444 patent expired on December 9, 2003; however, the '444 patent has effectively been extended by an additional 6 months of market exclusivity under Section 505(A) of the Act. Section 505(A) permits certain applications to obtain an additional 6 months of market exclusivity (pediatric exclusivity) if, in accord with the requirements of the statute, the NDA sponsor submits requested information relating to the use of ciprofloxacin in the pediatric population. Bayer submitted such information to the agency. The agency determined that this information met the criteria stated in the statute and granted Bayer 6 months of additional market exclusivity with respect to the '444 patent for its drug products containing ciprofloxacin. Therefore, final approval of your application could not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the period of market exclusivity (pediatric exclusivity) associated with the '444 patent expired, i.e., June 9, 2004.

1- Because information on the `754 patent was submitted before August 18, 2003, the references are to sections of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

With respect to 180-day generic drug exclusivity, we note that the former owner of this application was the first applicant to submit a substantially complete ANDA containing a paragraph IV certification to the `444 and `754 patents for the Ciprofloxacin Tablets USP, 100 mg. Therefore, with this approval, Dr. Reddy is eligible for 180 days of market exclusivity for the 100 mg strength only.

This exclusivity is provided for under §ection 505(j)(5)(B)(iv) of the Act.[2] The agency has concluded that the 250 mg, 500 mg, and 750 mg strengths are ineligible for 180-day exclusivity.

Please refer to 21 CFR 314.107(c)(4) with respect to the "first commercial marketing" trigger for the commencement of exclusivity. The agency expects that you will begin commercial marketing in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of the 100 mg strength of this drug 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

2- Because your ANDA was filed before the date of enactment of the MMA on December 8, 2003, this reference is to a section of the Act as in effect prior to December 8, 2003. See MMA §1102(b)(1). Note that because in this case there is no possibility of a court decision (see §ection 505(j)(5)(B)(iv)(II) as in effect prior to December 8, 2003), first commercial marketing is the only action by which exclusivity can begin to run.

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) 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